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July 3, 2024

In the Matter of

LEACHCO, INC., CPSC Docket No. 22-1

Respondent.

MEMORANDUM OPINION AND INITIAL ORDER DENYING RELIEF SOUGHT IN THE COMPLAINT

Before: Judge Young

This action was commenced by a complaint filed by Complaint Counsel for the Consumer Product Safety Commission ("CPSC" or "the Commission"), pursuant to 16 C.F.R. § 1025.11, on February 10, 2022. It was assigned to me for hearing and decision, pursuant to an interagency agreement between the Commission and the Federal Mine Safety and Health Review Commission.

The Complaint alleged that a line of infant loungers designed and manufactured by Respondent Leachco, Inc., ("Leachco") was a substantial product hazard as defined in Section 15 of the Consumer Product Safety Act ("CPSA"). Leachco denied the allegations in the Complaint, and a hearing was held August 7-10, 2023.[1]

[1] References to the four days of hearing transcripts begin with the transcript for August 7, 2023, cited as "Tr. Vol. I," and proceed through the transcript for August 10, cited as "Tr. Vol. IV." The exhibits in this case were consecutively numbered. In this decision, the Commission's (who was represented by Complaint Counsel) exhibits are referred to as CCX-1, CCX-2, etc. Respondent Leachco's exhibits are referred to as RX-1, RX-2, etc. Joint exhibits are referred to as JX-1, JX-2, etc.

In some cases, including the expert witnesses' reports, exhibits were attached to the exhibit, and/or tables or figures within the exhibit are being cited. In such cases, the full citation for the exhibit will be the exhibit as numbered by the party submitting it, followed by a reference to the exhibit number within the internal document (if applicable), and the figure or table number. *E.g.*, CCX-1, Ex. B, at 10-14, Table 1 (referring to Table 1 listed on pages 10-14 of the Exhibit B submitted as part of CCX-1).

I. Facts

A. Leachco and the Podster

1. Leachco

Leachco, Inc., is a small, family-owned business. The company was founded in 1988 by Jamie Leach and Clyde Leach. Jt. Stips., ¶ 1. Clyde Leach is Leachco's President and Chief Executive Officer, and Jamie Leach is Vice President and, as Chief of Product Development, designs Leachco's products. Jt. Stips., ¶¶ 5-7.

Leachco had total revenues of about $7 million in 2021 and $6.5 million in 2022. Tr. Vol. I, at 147; CCX-5, Clyde Leach Dep., Feb. 28, 2023, at 88. Leachco has about 30 employees and is based in Ada, Oklahoma. Jt. Stips., ¶ 8. It manufactures, distributes, and offers for sale more than 90 products for use by infants, children, and adults. Jt. Stips., ¶ 2. Its products are sold through retailers across the United States and on Leachco's website, www.Leachco.com. Jt. Stips., ¶¶ 3-4.

Jamie Leach attended nursing school and worked as a nurse before founding Leachco in 1988 with her husband. Tr. Vol. I, at 113. She does not currently have a nursing license and does not have a medical or engineering degree. Tr. Vol. I, at 113. She first designed the Podster in 1988. Tr. Vol. I, at 113.

2. The Podster Product Line

Included among these products is the "Podster" line of infant loungers, including the Podster, Podster Plus, Bummzie, and Podster Playtime models, all of which have been manufactured in Leachco's facilities in Ada. Jt. Stips., ¶¶ 9-10.

Since first being sold in 2009, approximately 180,000 Podsters have been manufactured and distributed by Leachco in commerce in the United States, at a retail price between $49 and $89 per unit. Jt. Stips., ¶¶ 12-14.

According to Leachco's marketing on its website:

> The Podster provides a warm and cozy caress for infants. The deeply contoured sides help keep the baby in place while the unique sling center expands with infant's weight. The adjustment tables provide versatile support, cinch them in to create a cozier and more secure seat for smaller infants or release them to create a larger area for growing infants. The Podster provides upper body elevation, which can help aid in digestion and breathing.
>
> [It] is specifically designed to help with daytime care of awake infants for the countless times each day when parents and caregivers need to free up their hands for the activities of daily life. The Podster provides a safe, secure spot to place an infant on its back as the parent or caregiver supervises hands-free, able to prepare a meal, pay bills, check email, give a hand to siblings, and many other daily tasks.

Jt. Stips., ¶¶ 15-16.

The Podster is not and never has been advertised by Leachco as a sleep product. Jt. Stips., ¶ 18. Leachco included numerous other, specific warnings and specific directions for safe use of the Podster, including that the product should not be used for sleep; that adult supervision is always required; and that it should only be used on the floor, and not placed in or on a bed, crib, playpen, table, or other elevated surface. Jt. Stips., ¶¶ 19-20.

Product warnings provided by Leachco with the Podster also state that it should only be used for healthy infants, not including "preemies" (a colloquialism for premature infants) not to exceed 16 pounds in weight and should not be used if an infant can roll over or push up on his/her hands and knees – whichever occurs first. Jt. Stips., ¶¶ 17, 22. Warnings further advise that infants should not be placed prone or on their side in the Poster, and that the Podster should never be moved with a baby in it. Jt. Stips., ¶¶ 17, 21, 22. Finally, Leachco warned that failure to follow the warnings and instructions could result in serious injury or death. Jt. Stips., ¶¶ 17, 23.

B. The CPSC Investigates and Takes Action After an Infant Dies.

1. The CPSC's Investigation of the Podster

The CPSC is authorized by the CPSA to investigate products in commerce to determine whether they present a substantial product hazard to the public. Tr. Vol. I, at 175. The Commission employes product safety investigators for this purpose when a product is implicated in a near injury, injury, or fatality. Tr. Vol. I, at 174.

The assigned investigator may interview consumers, police officers, medical examiners, and other investigating officials. Tr. Vol. I, at 174. The investigator will then prepare an In-Depth Investigation Report ("IDI") which will include factual data about accidents or incidents involving the product. Tr. Vol. I, at 174. The investigator assigned to review the Podster typically prepares between 50-75 IDIs per year. Tr. Vol. I, at 174.

The Commission is notified by medical examiners and coroners across the country when they encounter what may be a product-related fatality, through a program called the Medical Examiner and Coroner Alert Project ("MECAP"). Vol. I, at 176. CPSC Investigator Elizabeth Phillips received a MECAP report from Virginia after a three-month-old girl was found unresponsive on a Podster and died. Tr. Vol. I, at 176-77.

In the course of her investigation, Phillips collected a police report from the Lunenberg County, Va., sheriff's office and a pre-hospital emergency medical service care report from the fire department. Tr. Vol. I, at 177. She also spoke with the caregiver who had found the child unresponsive. Tr. Vol. I, at 177. The girl had been placed on her back on a Podster and had been left alone, sleeping, for 45 minutes. Tr. Vol. I, at 178-79.

When the caregiver checked on the child, he saw she had "slumped down a bit" and picked her up, intending to reposition her to make her more comfortable. Tr. Vol. I, at 179. When he saw that she was unresponsive, he began administering CPR. The girl was transported to the hospital but was dead on arrival. Tr. Vol. I, at 179.

Phillips said she identified the product involved as a Leachco product from photographs taken by the sheriff's department. Tr. Vol. I, at 195. Phillips identified the product as a Podster by researching it on Leachco's website. Tr. Vol. I, at 195.

2. A Complaint is Filed, Seeking a Recall, Prohibition on Distribution of the Podsters, and Other Relief.

On February 9, 2022, Complaint Counsel filed the administrative Complaint in this matter, seeking "public notification and remedial action to protect the public from the substantial risks of injury presented by various models" of the Podster. Compl., ⁋1. Complaint Counsel cited authority contained in Sections 15(c),(d), and (f) of the PSA, 15 U.S.C. § 2064(c),(d), and (f).

The Complaint acknowledged the extensive warnings provided with the product. Compl., ⁋⁋ 15-18. It conceded that the Podsters had never been advertised by Respondent as a sleep product. Compl., ⁋ 14. The Complaint also noted that Respondent had warned consumers that "use of the product in contravention of these warnings could result in serious injury or death. Compl., ⁋ 19.

Nevertheless, the Complaint alleged that it was foreseeable that caregivers would use the Podster without supervision and for infant sleep. Compl., ⁋ 20. Because the product appeared simple to use, was likely to be used frequently, and did not appear to be dangerous, caregivers might disregard or fail to fully read the instructions and warnings. *Id.*

The Complaint also postulated that caregivers might choose not to disturb infants who fell asleep on a Podster, might choose the Podster as a sleep product for infants who had trouble sleeping otherwise or appeared to be comfortable sleeping in the product, even if aware of the warnings against such use. *Id.*

Additionally, the Complaint said that caregivers who were traveling or experiencing significant financial hardship might allow infants to sleep on the Podster because they did not have a safe sleep product readily available. *Id.* Caregivers might also accidentally or intentionally sleep while an infant is on a Podster or might otherwise leave an infant unsupervised on a Podster. *Id.*

The Complaint said these scenarios created a danger because infants could roll or move into a position on the product where the Podster or another object, such as soft bedding, could obstruct the infant's mouth and nose, restricting airflow. Compl., ⁋⁋ 21-22, 24.

Alleged defects in the product's design, including its concave shape, thick, soft, padding, and lack of rigid underlying components could facilitate unsafe movements by an infant, who

could move off of the Podster of into a position on the Podster where the infant's mouth and nose would be obstructed. Compl., ¶¶ 25-29. The Complaint charged that the design of the Podster could allow infants to bend their knees and push off of the raised sides of the product and could allow an infant to roll—even if the infant would not be able to roll on a flat surface. Compl., ¶¶ 29-30. The design also could impede an infant's ability to self-rescue if it rolled or moved into a position where airflow was obstructed. Compl., ¶ 26.

Another potential risk cited was that the design could lead to unsafe bedsharing with adult caregivers, placing the infant at risk of suffocation through movement into a compromised position within or outside of the Podster, where soft bedding or another surface could obstruct the infant's airway. Compl., ¶¶ 31-33. If an infant's airway were to be obstructed, suffocation and death could result in as little as three to 10 minutes. Compl., ¶ 34.

The Complaint cited "at least two" fatal incidents it claimed were caused by the Podster's defects. Compl., ¶ 35. These included a 4-month-old who had been placed in a side-sleeping position or face-up on a Podster placed in a crib. Compl., ¶ 36. The child was found face-down on the Podster and later died of complications from asphyxia. *Id.*

A 17-day-old infant also suffocated after being placed face-up on a Podster in a bed, between two adult caregivers. Compl., ¶ 37. The CPSC alleged that the infant moved off the Podster into the adult bed and that one of the caregivers had rolled onto the infant and the Podster. *Id.*

The Complaint charged that "[t]he Podsters are a Substantial Product Hazard Because They Contain Defects That Create a Substantial Risk of Injury to the Public." Compl., Count I. The Complaint alleged that the cited design defects and the potential for foreseeable misuse by caregivers, "separately, and in combination, create a substantial risk of injury to infants because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise." Compl., ¶¶ 50-51.

The relief requested includes a determination that the Podsters present a "substantial product hazard" under the CPSA and that "extensive and effective" public notification was required to protect the public from the hazard posed by the product. Compl., "Relief Sought," at 9. It requested the Commission to order Respondent to notify all those who sell and distribute the Podsters, and all those to whom they have been sold; to immediately cease distribution of the product; to notify state and local public health officials; to provide broadcast and internet notice of the defects and associated injuries and illness associated with the defects; to provide mail notice to all sellers, distributors, and customers; and to refund the purchase price to customers and reimburse retailers and distributors for any expenses incurred by their compliance. Compl., "Relief Sought," at 9-10.[2]

The Complaint also demanded that Respondent submit a plan satisfactory to the Commission directing that the above steps be carried out in a timely manner and submit monthly reports documenting the corrective action program's progress. Compl., "Relief Sought," at 10.

[2] The remedies spelled out in the "Relief Sought" section of the Complaint are set forth in subsections 15(c) and (d) of the CPSA, 15 U.S.C. § 2064(c) and (d).

Respondent would also be required to keep and provide to the Commission records of its compliance actions and to keep the Commission informed of any changes in its business for five years after the issuance of the final order. *Id.*

C. Leachco Disputes the Complaint, and the Parties Proceed Toward Trial.

Respondent filed and served an answer to the Complaint on March 2, 2022. The answer denied the allegations in the Complaint and asserted as defenses a failure to state a claim, to identify a defect, substantial product hazard, substantial risk of injury to the public, as those terms are defined in the CPSA. Answer, at 6. The answer also averred that the Complaint failed to identify a risk of injury that outweighs the product's utility, that the alleged injuries suffered by children were caused by third persons over whom Respondent had no control or by misuse, unauthorized or unintended use, or by unforeseeable or improper use of the product, and that the Complaint was barred by waiver, estoppel, or laches. Answer, at 6-7.

After the answer was filed, the Pacific Legal Foundation assumed responsibility for Respondent's representation. Respondent thereafter moved to disqualify the hearing officer and to dismiss the Complaint on constitutional grounds. The motions were denied because a decision on them exceeded the authority conferred to the hearing officer.

After extensive discovery and numerous motions on disputed matters in that process, Respondent moved for summary decision and Complaint Counsel moved for partial summary decision (on the question of whether alleged defect in the Podsters created a substantial risk of injury to the public). Both motions were denied by Order on July 6, 2023 ("Summary Dec. Denial").

D. Complaint Counsel's Experts Develop a Theory That the Podsters' Design Creates a Substantial Product Hazard, While Respondent's Expert Challenges their Methods and Conclusions.

The parties' cases relied almost exclusively on expert testimony. The expert testimony was provided largely by detailed technical reports, with the proponent of the witness permitted to amplify the reports with live testimony, and the opponent permitted to cross-examine the witness.

1. Dr. Erin Mannen Testifies about Biomechanics, the Podster's Design and her Opinion on the Design's Effect on Infant Physiology.

Complaint Counsel tendered and qualified Dr. Erin Mannen as an expert in biomechanical engineering.[3] Mannen is a professor in the Department of Mechanical and

[3] Mannen has had an extensive relationship with the CPSC, including her leadership of several studies of the biomechanics of various infant products. On cross-examination, Respondent appropriately sought to impeach her based on this relationship. *See* Tr. Vol. I, at 153-54. The "Disposition" section of this opinion discusses critical issues that may affect her (continued . . .)

Biomedical Engineering at Boise State University. Tr. Vol. I, at 45. She is the director of the Boise Applied Biomechanics of Infants ("BABI") Lab at the university. Tr. Vol. I, at 45.

Mannen's focus of study and research is the motion of infants and their use of muscles, and the implications of infants' muscular-skeletal development for commercial products and safety. Tr. Vol. I, at 45. Mannen has authored more than 50 peer-reviewed publications relating to biomechanics. CCX-1, at 7.

Mannen's work includes a 2019 study, Erin Mannen, et al, Biomechanical Analysis of Inclined Infant Sleep Products (2019), (CCX-1, Ex. B),[4] which she produced as leader of a team of clinicians, researchers, and engineers. CCX-1, at 8. The study analyzed the design of 14 infant sleep products and determined that "a range of product designs and incline angles were present in the product class." *Id.* The study included non-invasive study of live infants aged two to six months. *Id.*

The study used a variety of techniques and sensors to evaluate both the incline aspect of the products and other design features. CCX-1, at 9. *See also* CCX-1, Ex. B. The products were compared to an inclined sleep mattress to isolate the incline from other factors that might affect infant performance. CCX-1, at 9. The study then considered how various designs impacted movement and muscle activity of infants. *Id.*

In its background, the 2019 study noted that:

> Since 1992, the American Academy of Pediatrics (AAP) has recommended that infants under the age of one should be placed for sleep on a flat and firm surface in the supine position to reduce the incidence of Sudden Infant Death Syndrome (SIDS). The rate of SIDS deaths has decreased by 70% [sic] since the National Institute of Child Health and Development (NICHD) "Safe to Sleep" campaign (formerly "Back-to-Sleep") was implemented in 1992. [Internal note omitted].[5]

CCX-1, Ex. B, at 3.

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[3] (. . . continued)
conclusions or the relevance of her opinion, but nothing in her testimony, her report, or her scholarship betrays any undue influence by the CPSC on her research or any other research integrity issues.

[4] Mannen authored two studies that were included as exhibits to her testimony. To avoid confusion and promote readability, only the exhibit numbers will be cited after the first reference to each study.

[5] Somewhat incredibly, the rate of infant deaths in 1992 by what was then known as SIDS and is now known as "Sudden Unexpected Infant Death" ("SUID") was 120 deaths for every 100,000 live births. By 2019, this rate had been reduced by nearly *75%*. Tr. Vol. III, at 29-30. The AAP effort is probably one of the most impressive public health campaign results in U.S. history and has commendably helped prevent the tragic premature deaths of thousands of infants.

The study went on to note that some infants were placed in inclined sleep products, which are designed to keep infants in a supine position, inclined at an angle of 10 to 30 degrees. *Id.* These products "do not meet safe sleep guidelines set forth by the NICHD and the AAP" and "several infant deaths have been reported in Inclined Sleep Products with the deceased infants often found in the prone position, with suffocation as the apparent cause of death." *Id.*

The 2019 study was designed to determine "if the *design* of the Inclined Sleep Products contribute [sic] directly to an increased rate of infant deaths by either making it easier to roll from the supine to the prone position or making it more difficult to self-correct from the prone to the supine position." *Id.* (Emphasis in original). The study hypothesized that "[m]ovement demands based on a product design or body position may have a direct relationship to an infant's risk of suffocation due to inability to maneuver into a safe breathing position." *Id.*

Mannen evaluated two models of the Podster—the standard model and the "Podster Plush." Exemplars of each model were admitted by agreement of the parties as JX-1 and JX-2. Mannen tested 10 Podsters, five of each model. The two models are structurally indistinguishable and differ only in the textured, 100-percent polyester cover used on the Podster Plush. Tr. Vol. I, at 45-46.

All 10 Podsters were substantially similar. Tr. Vol. I, at 46. Based on her review of the product, Mannen concluded that "the Podster introduces significant hazards related to suffocation and positional asphyxiation for babies." Tr. Vol. I, at 46.

Mannen prepared an extensive report and numerous videos in support of her conclusion. The report was admitted as CCX-1. Tr. Vol. I, at 48. The videos were played at the hearing, and Mannen testified that they accurately represented her evaluation and testing of the Podsters.

The videos were made using mannequins, referred to as "CAMI Dolls," and hinged positioning models to represent the position of an infant on the Podster. Exhibit CCX-44 showed the intended supine positioning of an infant on the Podster, while Exhibit CCX-45 showed the infant positioned in a slouched position on the product. Tr. Vol. I, at 51-53.

Exhibits CCX-46 and CCX-47 demonstrated the hip and trunk flexion of an infant on the product in the supine and slouched positions, respectively. Tr. Vol. I, at 54-56. Exhibits CCX-48 and CCX-49 demonstrated infant head-neck flexion and sagittal plane flexion on the Podster. Tr. Vol. I, at 56-59.

Mannen used segmented models to simulate infant positioning in her evaluation. Tr. Vol. I, at 60-61. The hinged devices were designed by a team of biomechanists, engineers, and clinicians for use in a 2022 study of infant pillows not intended for use in sleep, including the Podster, that she led for the CPSC. Tr. Vol. I, at 98; Erin Mannen, et al, United States Consumer Product Safety Commission Technical Reports, Pillows Product Characterization and Testing, (2022) (CCX-1, Ex. C).

The devices were used to show the movement of the head, hinged to the upper torso/thorax, which is hinged to the lower torso, which is hinged to the segment representing the legs. Tr. Vol. I, at 60; CCX-1, at 16-17. The design is anthropometric, so that the weight, length, height, segmental length, and width are equivalent to those of a newborn infant, and an infant at approximately six months old. Tr. Vol. I, at 60; CCX-1, at 16-17. Mannen positioned the devices on the Podster models in an initial position she determined by viewing photographs on Respondent's website, and then positioned the models in a "slouched" position. CCX-1, at 17-18.

"CAMI dolls,"[6] which more closely resemble three-dimensional infants than the hinged devices, were used to more accurately duplicate "the more complex, three-dimensional nature of the head/neck complex and the back of the head." CCX-1, at 19. Again, distinct CAMI dolls were used to approximate the size and weight of newborn and six-month-old infants. *Id.*

Mannen used the devices and an inclinometer to compare the placement of an infant in a Podster to the placement of an infant on a flat, firm surface and found that the Podster permitted "significantly increased trunk flexion angle" in the slouched position. Tr. Vol. I, at 61-62; CCX-1, at 19-20, 34-35; CCX-1, Fig 5.

Mannen focused on trunk flexion because it is "known to affect breathing." CCX-1, at 16. She determined this by considering movement permitted within the "sagittal plane," a term used to describe an imagined bisection of the human body's right and left halves. Tr. Vol. I, at 62. Within that plane, the trunk flexion permitted approximated the movement in an abdominal crunch exercise. Tr. Vol. I, at 62. Depending on the position of the infants within the Podsters, she concluded that the Podsters would permit trunk flexion from 32-49% greater and hip flexion up to 58% greater than if the infant were on a firm, flat crib mattress.

Mannen demonstrated the device in the courtroom and said that the test procedure she used in the demonstration was the same as the one used in the video, except that the video used an inclinometer (a device used to show degree of incline on a surface) to show the angle of repose. Tr. Vol. I, at 63. Videos were admitted showing firmness tests for the Podster using disc testing and vertical lift devices. Tr. Vol. I, at 63-66; CCX-50; CCX-52.

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[6] According to the manufacturer of one type of CAMI doll, the infant-sized dolls were developed to evaluate child-restraint systems:

> The CAMI (Civil Aeronautical Medical Institute) Newborn Infant and 6-Month-Old Infant ATDs were developed for the evaluation of child restraint systems as defined in CFR 49, Part 571, Standard No. 213. The dummies consist of steel and aluminum weights attached to leather skeletons wrapped in layers of foam padding and covered with a stitched cloth outer shell.

CAMI Mark I & II, Humanetics, https://www.humaneticsgroup.com/products/anthropomorphic-test-devices/child/cami-mark-i-ii (last visited July 1, 2024). *See also* Tr. Vol. I, at 112. The dolls are sized at the 50th percentile for height and weight. *Id.*

Admitted video exhibits also showed airflow and head rotation tests Mannen performed on the Podster. Tr. Vol. I, at 66-69; CCX-52; CCX-55. Mannen also tested the firmness of the Podsters using a modified firmometer to assess the products' firmness in a pass-fail test. CCX-1, at 21-23. "A product that is dangerously soft will fail this test, meaning that it deforms too much under a load." CCX-1, at 21.

"When you consider that this load may be an infant's face, it is easy to understand that a product that is too soft will deform too much and will envelop an infant's face if they [sic] are prone on the product or the infant's face is pressed against the side of the product, inhibiting breathing and increasing the risk of suffocations." *Id., citing* Expert Testimony of Dr. Umakanth Katwa (introduced as CCX-3).

The safety threshold used was the approximate measured firmness of a flat, firm crib mattress. CCX-1, at 23-24. Mannen determined that the Podsters failed the firmness test because a feeler arm attached to the firmometer contacted the side of the Podster during the test. CCX-1, at 22, Fig. 7.

In addition to firmness, Mannen tested the Podsters for airflow to evaluate the possible risk of suffocation. CCX-1, at 24. Airflow testing is used to determine whether an infant, with limited control of its head and neck movements, would receive sufficient air exchange through the product if the infant is face down or if the infant's face is in contact with the side of the product. *Id.* Mannen noted that at the extremes, mesh, with holes throughout the fabric, is considered a safe material to breathe through, while a plastic bag is not. CCX-1, at 24-25.

Mannen used an airflow test method based on BS (British Standard) 4578:1970. CCX-1, at 25, Fig. 9. Compared to the airflow permitted by a mesh-like material, the air pressure reading for the Podsters (which is inverse to the airflow, such that a lower pressure reading permits higher airflow), she found that test results on the pillow portion of the Podster "were much higher and most concerning." CCX-1, at 25.

Mannen also analyzed the Podster in comparison to the inclined infant sleeping products she had evaluated using live human infants and said the design of the Podster facilitated infants rolling in the Podster. Tr. Vol. I, at 69-70; CCX-56.

IDIs were introduced as exhibits for incidents where a Podster had been present when an infant died in Alabama (the "Alabama IDI," marked as JX-6), Texas (the "Texas IDI," marked as JX-8), and Virginia (the "Virginia IDI," marked as JX-10). Tr. Vol. I, at 72-75.[7] Mannen reviewed the IDIs for her report. Tr. Vol. I, at 72-75. She testified that the IDIs would be helpful to members of the biomechanical engineering field in determining whether the Podster was hazardous. Tr. Vol. I, at 72-75.

[7] Exhibit cite references are to redacted versions of the IDIs provided for the public record. Unredacted versions were produced for *in camera* review as JX-7, JX-9, and JX-11, respectively.

Mannen's testimony essentially verified the videos and testified as to their usefulness while also demonstrating the items she used during the testing. The main findings and conclusions are contained in her extensive report. *See* CCX-1.

On cross-examination, Mannen acknowledged that she had not tested the Podster with live infants, stating that she had been able to compare the results of her test with another study she performed, using live infants, in testing infant sleep products for the CDC. Tr. Vol. I, at 79-80. She also acknowledged testing infants on crib mattresses at various inclines. Tr. Vol. I, at 80.

The CPSC commissioned four multi-disciplinary reports by a team that Mannen led as the principal investigator, studying a number of infant products, from 2019-2023. Tr. Vol. I, 83-84. None of the studies was peer reviewed. Tr. Vol. I, at 84-85. But two papers she co-authored,—Junsig Wang et al, Do inclined sleep surfaces impact infants' muscle activity and movement? A safe sleep product design perspective, 111 J. Biomechanics (2020); and Junsig Wang et al., Infant inclined sleep product safety: A model for using biomechanics to explore safe infant product design, 128 J. Biomechanics (2021) (introduced as RX-34 and RX-35, respectively)—had been peer-reviewed. *Id.*

RX-34 studied the muscle activity of healthy infants lying supine (on one's back) and prone (face-down) on crib mattresses at different inclines. Tr. Vol. I, at 85. RX-35 viewed the same subject, studying infants on various inclined sleep products. Tr. Vol. I, at 86.

Mannen's report also compared the Podsters to inclined sleep products, including back and thigh angles and how the infant was positioned on the products. CCX-1, at 13. Common testing methods included the use of the infant-sized and -weighted hinged models to test incline and simulated positioning for all 10 Podster units placed on a flat wooden floor. CCX-1, at 14-15.

The papers compared the results for infants on a mattress to those for infants on the inclined sleep products. *Id.* But there was no statistical analysis performed of the relative differences between the three infant sleep products studied. *Id.*

Mannen was cross-examined extensively on the number and value of various contracts she had with the CPSC before, during, and after her preparation of her report in this case. When questioned about RX-34 and RX-35, Mannen acknowledged that they focused on the difference between a firm crib mattress and the three infant sleep products studied. Tr. Vol. I, at 95-97. She agreed that the study of infant sleep products stated that those products had "varying characteristics such as plush materials, conforming designs, seat features, and curved surfaces, all which present a mechanical environment different than a firm and flat inclined crib mattress." Tr. Vol. I, at 96. She acknowledged that the nature of the subject prevented a comparison of the different inclined sleep products against one another. Tr. Vol. I, at 97-98.

Mannen also conceded limitations in some of the testing methods and devices she used. Tr. Vol. I, at 97-115. In particular, she agreed that the four-segment device was being improved to better represent infant movement, and that the modeling devices used did not fully replicate

head and neck flexion. Tr. Vol. I, at 107-09. She acknowledged the lack of a "safety threshold" for head-neck flexion. Tr. Vol. I, at 110. And she agreed that head-neck flexion and trunk flexion would not be identical on the four-segment sagittal plane device, the CAMI Doll, and a live infant. Tr. Vol. I, at 116-17.

Respondent also questioned Mannen thoroughly on the studies she had participated in and relied on. Tr. Vol. I, at 143-49. She acknowledged that some of the studies included adults or focused on infants too old and thus too large to use the Podster, and that some movement patterns were most often exhibited by those older children. Tr. Vol. I, at 143-49.

No test results showed an infant's face in contact with the sides of the Podster when in the intended position. Tr. Vol. I, at 125-126. Because Mannen did not use live infants in her studies of the pillow products or the Podsters, she never observed an infant sliding into the slouched position. Tr. Vol. I, at 125-126. But she did believe that the infant in the Virginia IDI had been found in a side-lying, slouched position. Tr. Vol. I, at 126.

One factor Mannen considered to be important is the proper exchange of gases during breathing, because increased carbon dioxide levels could lead to hypoxemia, and decreased oxygen levels could lead to hypoxemia and, eventually, hypoxia. Tr. Vol. I, at 133.

Carbon dioxide (CO_2) retention by infants was not specifically evaluated for the Podster. Tr. Vol. I, at 133. However, Mannen did test for rebreathing by using a weighted doll, with simulated nostrils and gases at a controlled concentration to simulate breathing into the Podsters. CCX-1, at 27-28, Fig. 10.

Mannen also compared rebreathing on a flat crib mattress with a cotton sheet to the Podster. *Id.* However, the modeling was not done with live infants. Tr. Vol. I, at 135. Mannen acknowledged that this limited the utility modeling and its application to determine the effect of rebreathing in any specific case involving an actual infant. Tr. Vol. I, at 136-38.

Head rotation and movement from the supine and prone positions on the Podsters were also considered. CCX-1, at 28-31, Figs. 11 and 12. Mannen agreed that she had not witnessed any infants rolling in her 2019 study of infant sleep products, but relied on her knowledge of biomechanics to predict how infants could roll. Tr. Vol. I, at 142-43. She said the design of the Podster, and the degree of hip-trunk flexion it created, made it easier for infants to roll a certain way on the product. Tr. Vol. I, at 143.

Mannen concluded from her review of the testing she and her team conducted that the "head and thigh angles of the Leachco Podster are similar to dangerous inclined sleep products," and found the similarities to be "obvious." CCX-1, at 32. She found the similarities sufficient to conclude "that the Leachco Podster is dangerous in manners similar to how those inclined sleep products were found to be dangerous." CCX-1, at 33.

In addition to comparing the Podsters to infant sleep products she had previously studied, Mannen also analyzed body position relative to a firm, flat crib mattress. CCX-1, at 34-35. She found significantly greater trunk and hip flexion on the Podster, even when the model was placed

in a position recommended by the manufacturer. CCX-1, at 35. Head-neck flexion in the Podster was similarly greater than on the mattress, in both the intended and slouched position. CCX-1, at 35-36.

Mannen discerned from her test results that the body position on the Podster inhibits normal breathing. CCX-1, at 37. She again concluded that the positioning was like that of infants "lying supine within dangerous inclined sleep products." *Id.* She found the body positioning and flexion to "have negative implications for breathing, especially for vulnerable infants with developing respiratory systems." CCX-1, at 38. *See also* Tr. Vol. I, at 164 (noting on redirect that an infant's respiratory system is much less developed than an adult's).

Mannen said that "the Leachco Podster represents a different and more problematic mechanical environment than a firm and flat crib mattress," and that the Podster is therefore not equivalent to that environment. CCX-1, at 38-39. She relied on measurements of the CAMI doll in the Podster in comparison to live infants she had observed in the inclined sleep product study. CCX-1, at 39. Mannen said that researchers had observed reduced lung capacity and lower expiratory flow as compared to a standing position. *Id.*

While some research was performed on adults, Mannen said that the inclined posture in the Podster, which could not be considered a "lying position," was "even more concerning compared to adults with fully developed respiratory systems." CCX-1, at 40.

Mannen also testified that the design of the Podster facilitated rolling on the product, even in infants who could not roll on a flat surface. CCX-1, at 41-43. Explaining the body mechanics of infant movement and rolling, she said the "design of the Podster product removes the necessity to complete the entire sequence of coordinated movements normally required to achieve a roll on a flat surface due to the different mechanical environment." *Id.* This rolling on or off the Podster could create a risk of the infant ending in a prone position in an unsafe environment and could cause oxygen levels to dip below safe thresholds "in a very short amount of time," due to rebreathing. CCX-1, at 43.

According to Mannen, the Podster's design also causes muscle fatigue and inhibits an infant's ability to self-rescue after rolling to a prone position. CCX-1, at 44. She relied heavily on previous research involving inclined sleep products, which she said showed significantly greater abdominal muscle activity as compared to lying on a flat, firm mattress. *Id.* She testified that this increases the danger of suffocation because the same muscles needed to roll back to a supine position are used for breathing. CCX-1, at 44-46.

Mannen also characterized the Podster as "dangerously too soft." CCX-1, at 46. She said that airflow and rebreathing testing showed that the Podster exhibited approximately one-tenth of the recommended airflow threshold identified in a previous study of other products and that CO_2 rebreathing was nearly 2.5 times as great on the Podsters, increasing the risk of hypoxia. CCX-1, at 48-50.

A review of infant head rotation using the CAMI dolls prompted Mannen to assert that the Podster's design could result in contact with the padded side of the product with much less

head rotation than a flat mattress while in the supine position, while requiring a much greater degree of head rotation to break contact with the side of the product from a prone position. CCX-1, at 52-57. "The inability to move out of dangerous positions poses a serious risk of suffocation via CO_2 rebreathing and/or lack of airflow." CCX-1, at 57. In conclusion, Mannen agreed with the conclusion reached by another of the Commission's expert witnesses, Dr. Umakanth Katwa, about the suffocation risk posed by the product. CCX-1, at 58.

After reviewing the testing and incident history of the Podsters, Mannen said, "None of the tests Leachco conducted with respect to the Podster are [sic] sufficient to identify the dangers related to movement, body position, or breathing from a biomechanics perspective." CCX-1, at 59. She said that she independently reviewed the three IDIs for deaths where a Podster had been present and appeared to have been used in an unsafe sleep environment. Her opinion—which she said did not consider the opinions of the CPSC staff who prepared the IDIs—was that the scenarios resulting in the deaths of the three infants were consistent with her observations about the dangers of the Podster. CCX-1, at 59-61.

Mannen's conclusion summed up her concerns about the product by stating that "the design of the Leachco Podster introduces significant risk for infants because it affects their ability to move and breathe and thereby increases their risk of injury or death." CCX-1, at 61.

2. Elizabeth Phillips Explains Her Investigation for the CPSC.

Phillips has been a product safety investigator for the CPSC for 27 years. Tr. Vol. I, at 173-74. As such, she reviews incidents involving injuries, near-injuries and fatalities. Tr. Vol. I, at 174. In performing her duties, Phillips may interview consumers, police officers, medical examiners, and others who may have information or data about the targeted scenario. Tr. Vol. I, at 174.

As noted above, Slip Op. at 3, *supra*, product safety investigators routinely produce IDIs to document an incident related to a product and to determine whether a product has a substantial product hazard. Tr. Vol. I, at 175. Phillips investigated an incident in Lunenberg County, Va., and prepared the Virginia IDI (introduced as JX-10).

A three-month-old girl had been placed on her back in a Podster inside a crib in an in-home day care facility. Tr. Vol. I, at 178-79. She was left unattended for approximately 45 minutes. Tr. Vol. I, at 179. When the caregiver checked on her, he discovered that the girl was "limp" and "lifeless." Tr. Vol. I, at 179. She was transported to the hospital but was pronounced dead on arrival. Tr. Vol. I, at 179.

Phillips identified the Podster as a Leachco product from photos taken by sheriff's deputies at the scene. Tr. Vol. I, at 180. The medical examiner had provided a MECAP report to the CPSC, which initiated the investigation. Tr. Vol. I, at 181-83. Phillips' investigation included reports of interviews with the caregiver, body camera footage, government reports from the sheriff's office and emergency medical service workers who provided pre-hospital care. Tr. Vol. I, at 190. She also obtained photographs from the county, which had been taken by the sheriff's office, in addition to their report. Tr. Vol. I, at 193-94.

As part of the IDI, Phillips prepared an infant suffocation data record sheet. Tr. Vol. I, at 196. This is prepared when there is an infant suffocation, and includes the height and weight of the child, the product(s) involved, and other circumstances. Tr. Vol. I, at 196.

The IDI and the documents collected during the investigation were admitted over numerous hearsay objections as part of the record of the case.

3. Celestine Kish Characterizes Warnings as "Last Step in the Hierarchy of Hazard Control," and Testifies that Consumers Will Not Heed Warnings Against Misuse.

Celestine Kish has been a senior engineering psychologist in the Division of Human Factors at the CPSC since 1999, and first joined the Commission in 1988. CCX-2, at 1. She has a Master of Arts degree in Industrial/Organizing Psychology. CCX-2, at 6.

The Division of Human Factors is within the Commission's Directorate of Engineering Sciences, which manages rulemaking and develops mandatory and voluntary product safety standards. CCX-2, at 2. It also conducts product safety assessments ("PSAs"), analyzes recall remedies, and provides litigation support for the Commission's Office of Compliance and Field Operations. *Id.*

The Division of Human Factors uses principles of human factors psychology and engineering to determine how humans interact with consumer products, and how that interaction may affect errors, incidents, and resultant injuries and deaths. *Id.* Kish's primary focus in her work is products intended for infants, toddlers, and children. CCX-2, at 3. She has "generally served as the Human Factors expert on children's products" for the Commission, and has managed research and risk reduction projects, developed technical requirements and test methodologies for product safety standards, and conducted PSAs of children's products. *Id.*

Kish has been project manager for projects dealing with a variety of products, including mandatory safety standards for bassinets, bedside sleepers, booster seats, infant bath seats, infant bathtubs, infant sleep products (including inclined sleep products), and toddler beds. *Id.* She also managed the rule requiring products covered under Section 104 of the CPSA to include a project registration card so that consumers can be notified if a product is recalled. *Id.*

As a member of the Infant Loungers Subcommittee for the ASTM International ("ASTM"), she has been working to develop a voluntary industry standard for products like the Podster. CCCX-2, at 5. She reviewed the entire Podster product line, but said her understanding was that the Podster Bummzie and Podster Playtime models were discontinued in 2018 and 2017, respectively. CCX-2, at 6.

The lounger portions of all Podster models are essentially similar and consist of a U-shaped interior pillow and a zippered, removable cover. *Id.* The infant sits in the middle of the pillow, on a single layer of elastic fabric. *Id.* Kish noted that Respondent says on its website that the Podster is an infant lounger "designed to help with daytime care of awake infants for the

countless times each day when parents and caregivers need to free up their hands for the activities of daily life." CCX-2, at 6-7.

Kish asserted that the Podster's warning system fails to protect infants from hazards. CCX-2, at 7. Her assessment rests on the notion that "seeing, reading, and understanding a warning on a consumer product is just the first step. The warning must also motivate the consumer to change his/her behavior towards that consumer product and heed the warning." *Id.*[8]

She identified two product hazards from use of the Podster: (1) suffocation; and (2) falling (if the Podster is placed on an elevated surface). Tr. Vol. II, at 23. In determining the hazards, Kish said she did not consider the number of products available so much as the potential for injury from use of the product. Tr. Vol. II, at 27.

Kish said that warnings may not protect against misuse because prior experience with a product, or a product that seems to be similar, is inconsistent with the warning label or its portended consequences can decrease a warning's effectiveness. CCX-2, at 7-8. This may be dangerous if the products are *not* similar, i.e. if one product is different in a way that makes it more hazardous. CCX-2, at 7-8. Kish also suggests that parents may assume that a product marketed for use with infants is safe. CCX-2, at 8.

Kish discussed factors that could affect the utility or reception of warnings. The person must be "alert and sober," and willing to seek out information and not filter out the warning. CCX-2, at 8, Fig. 2. Over-warning is, ironically, a problem. *Id.* Labels and signs need to be used only where and when needed, include only the information needed, and be in an appropriate, noticeable format. *Id.*

The person receiving the warning must also be motivated and able to change behavior, such that they would not be aware of the hazard without the warning, would believe the warning and credit the source, the conduct of others, or experience to heed the warning. *Id.* The person reading the warning must decide not to accept the risks because of a serious appreciation for the consequences of not doing so and a recognition that the risk is not within the person's ability to control and outweighs internal and external pressures to assume the risk. *Id.*

Kish cited to "optimism bias"—a consumer's belief that negative consequences will not befall them. CCX-2, 9. This lessens a consumer's motivation to heed warnings. *Id.* Kish claimed that the warnings for the Podsters "fail to meet minimum accepted design requirements to be noticed, read and understood by consumers." *Id.* But even if properly designed, consumers would not be motivated to heed them because of other factors. *Id.*

Warnings are "the last step in the hierarchy of hazard control," because motivating consumers to change behavior can be difficult, and inherent flaws in warning messages advise in favor of (1) "designing out" the hazard, or (2) guarding against hazards as primary and secondary

[8] Kish cites to Allison G. Vredenburgh and Jessica Helmick-Rich, Extrinsic Nonwarning Factors, *in* Handbook of warnings 352 (M.S. Wogalter, ed., 2006): "Even when warnings capture attention, and are read and understood, existing attitudes and beliefs, consistent with expectations, can conflict with the warning message."

approaches. *Id.* Because of the environmental factors and the knowledge, beliefs, and characteristics of the consumers involved, the warning itself is only one part of the process of hazard control by warning against dangers. CCX-2, at 10. Thus, while Kish said she believes Leachco's warnings were inadequate because they did not meet (voluntary) ANSI Standard ANSI Z535.4,[9] "*no* warning label for the Podster would have sufficiently addressed and mitigated the safety hazard presented by its foreseeable uses." *Id.* (emphasis added).

Kish acknowledged the warnings that were described in the Complaint, against using the product for sleep, or with premature infants (those born at or before 37 weeks of gestational age), and requiring adult supervision at all times, with the Podster to be placed only on the floor, and never in a crib or playpen or on any elevated surface. CCX-2, at 12-13.

Warning labels are placed on the packaging, on the cover, and on the inside pillow. CCX-2, at 12-14. Kish included photographs of Respondent's warnings as figures in her report. CCX-2, at 12-17, Figs. 5-10.

When surveyed, consumers have said they are less likely to perceive a product as hazardous and heed their warnings if they use it frequently, or when products are more familiar, easier to use, safer, or cheaper. CCX-2, at 18. To counter these problems, and others, warnings must be easily observable and memorable. *Id.* Kish cited literature advising label design to promote salience, wording, layout/placement, and the use of pictorial symbols. *Id.* (footnote omitted). She also cited to ANSI guidelines for design, application, use, and placement of warnings. *Id.*

Labels should "stand out," using bright colors for the label or bold or red text, for example. CCX-2, 19. The warning must appropriately label hazards with "Danger," "Warning," or "Caution" and should use clear terms and a "safety alert" signal.[10] CCX-2, at 19-20, Fig. 11. Warning text should be explicit, complete, and concise, and should describe the hazard, the consequences of not avoiding it, and how to avoid it. CCX-2, at 20. Warnings must be complete enough to advise of the danger, but not so long that people will not read it. *Id.*

Warning layout and placement are also important. A "bullet" or outline format is preferred. CCX-2, at 21. The label should be located where consumers are most likely to notice and read it. *Id.* Pictorial symbols may be effective if they convey the hazard, and placing labels on multiple locations will improve the odds the warning will be noticed by consumers. CCX-2, at 22.

Kish faulted the warning on the Podster packaging as not conforming to these guidelines. CCX-2, at 23-24, Fig. 12. The text is small, consisting of a block paragraph of black text with no pictorial symbols. CCX-2, at 23. There is a capitalized warning at the beginning, under the

[9] "ANSI" stands for the American National Standards, Institute, Inc. The standard was introduced as Exhibit 4 to CCX-2.

[10] A "safety alert" signal is a triangle with an exclamation point inside. *See* CCX-2, at 19-20, Fig. 11.

headline, that says "WARNING: TO PREVENT SERIOUS INJURY OR DEATH:" CCX-2, at 23, Fig. 12.

The warnings on the product itself do include some of the features recommended by ANSI and Kish, including a safety alert signal, a pictorial advisory against using the product for sleep, a larger "WARNING" advisory in a box, and, on one label, the use of an outline format. CCX-2, at 25-26, and Figs. 13 and 14. But all the print on the product warning labels is black text, and there is no color enhancement on the labels. *Id.*

Literally by way of contrast, Kish highlighted the use of the "safety orange" color to highlight the "WARNING" and safety alert signal in two otherwise indistinguishable sample crib warnings as almost-universally being recognized as more attention-grabbing. CCX-2, at 27, Fig. 15.

Kish also noted that while one version of the inner pillow warning includes an express warning of the hazard of suffocation, the other product warnings do not explain how death could result from use of the product. CCX-2, at 27. She cites this as a critical omission. CCX-2, at 28. But Kish also noted the "multiple types" of hazards the product could present and criticizes the failure to explain and distinguish the hazards associated with different types of misuse. *Id.*

The labels also include information Kish deemed non-essential and fail to prioritize the identification of hazards. CCX-2, at 29. This leads consumers to view warning labels as "boilerplate language that is put on every product for liability purposes." *Id.* (citation omitted). She also cites language that is ambiguous, either because different language is used on the same product, or because the term "pillow" is used instead of Podster, in relation to sleep environments. CCX-2, at 30.

Kish asserted that the inadequacy of the warning labels is important because the Podster is a soft, portable pillow that does not appear to be dangerous. CCX-2, at 31. Its simplicity promotes repeated use by consumers with young infants, and it is similar enough to an ordinary pillow that consumers may not seek out or heed warnings about potentially dangerous misuse. *Id.*

Kish advanced an intriguing concept as part of her theory: she characterizes certain forms of social influence on behavior as "pacifiers" that may affect the tendency to follow warnings. *Id.* The compliance or non-compliance of others with warnings or rules may have a "potent" influence on behavior. *Id.* Kish testified that no warnings could make the Podster safe because of these pacifiers. Tr. Vol. II, at 37.

Kish extended this social influence to today's environment, where social media examples are readily available for almost any activity, and where people literally position themselves as "influencers" modeling behavior in a variety of contexts. CCX-2, at 32-33. She argued that channels such as social media sites can be detrimental to the effectiveness of warnings by "pacifying" any concerns a consumer might have about misuse. CCX-2, at 32.

Kish stated that consumers are "inundated" with such counter-examples and their pacifying effect concerning infant sleep products in general, and the Podster in particular. CCX-2, at 33-34. She testified that these examples likely decrease the effectiveness of the Podster's warnings. CCX-2, at 34. Even parents who are aware of safe sleep recommendations may perceive the risk of injury as low and "are more likely to disregard safe sleep recommendations as they gain their own parenting experience." *Id.*

Conflicting sources on safe sleep practices for infants include advertisements stories featuring "celebrity parents" and retail crib displays showing unsafe sleep environments. CCX-2, at 34-35. Up to 40% of advertisements for infant sleep products may show an unsafe sleep environment. CCX-2, at 35.

In a 2017 study, Worcester Polytechnic Institute and the CPSC analyzed impediments to parents following the AAP's safe sleep recommendations to reduce the risk of Sudden Unexpected Infant Death (SUID). CCX-2, at 36. A focus group of seven mothers with at least two children each revealed nine barriers to following the AAP recommendations including desperation for sleep; a lack of safe alternatives to bedsharing, which some mothers practiced despite awareness of the risk, information overload; a lack of currency among older caregivers; unsafe depictions and influence from peers and consumer reviews; and a lack of national parental leave in the U.S. CCX-2, at 36-37.

A 2019 study by Fors Marsh Group found that caregivers were not likely to read warning labels, which were perceived as being "all the same" or written simply to protect manufacturers from liability. CCX-2, at 37. Caregivers were also highly likely to rely on their own contrary experience or the experience of others they knew, instead of following safe sleep recommendations. CCX-2, at 37-38.

Both studies found caregivers were likely to defer to consumer reviews from experienced parents and to prioritize environments and practices that permitted their infants to sleep. CCX-2, at 38. This included inclined sleepers. *Id.* Reviews on retailer websites often promoted unsafe sleep practices that are contrary to manufacturers warnings and recommendations. *Id.* Consumers also rely on social media, internet fora, or "mom blogs" for information. *Id.*

Kish said her review of social media and other internet sources showed that the "real-world" examples of how consumers discuss the Podsters validated the studies' findings. CCX-2, at 39. On Instagram, a search for the product produced 24 images, only six of which showed the Podster being used as intended. CCX-2, at 39-40, Fig. 16. Examples included comments endorsing the product for sleep without any response comment by Respondent. CCX-2, at 40-41, Fig. 17.

Kish characterized the images as "a significant, alarming pattern of counter-examples pacifying dangerous consumer use of the Podster," and diminishing the effectiveness of product warnings. *Id.* However, on cross-examination, she acknowledged not knowing how many consumers actually viewed the posts or images she found to be "alarming," and did not quantify or define what constituted an "alarming pattern." Tr. Vol. II, at 45-47.

Kish said that social media influencers can have an outsized effect on consumer behavior. CCX-2, at 41. Along with consumer reviews suggesting the product may be safely used for sleep, and the absence of any comment or caution from Respondent could persuade members of the public to disregard the product warnings. CCX-2, at 42. Again, though, Kish could not quantify or validate the effect any of the social media postings may have had on consumers. Tr. Vol. II, at 48-50.

Internet reviews of the Podsters "encourage consumers to use the Podster in an unsafe manner for both infant sleep and co-sleeping." CCX-2, at 42. These included reviews from reputable sources, such as a product review blog, which hailed the Podster as a "magical pod-**napper** sling contraption." *Id. citing,* Natalie Krinsky, This Pod Snuggles My Baby While I drink Rosé, N.Y. Magazine The Strategist, (Nov. 22, 2016) https://nymag.com/strategist/2016/11/the-best-baby-lounger-is-the-Leachco-Podster.html (emphasis shown in testimony).[11] On cross-examination, Kish admitted that she did not know the circulation of *New York Magazine*, how often it reviews consumer products, and whether those reviews are generally relied on by consumers. Tr. Vol. II, at 49-50.

Similarly, Kish noted that a review posted at *The Stork List* promoted the use of the Podster for co-sleeping and touted the Podster as "a great place for your baby to sleep or comfortably sit and play during awake hours." *Id.* (discussing What is the Best Co-Sleeper? Leachco Podster vs. Bobby Lounger vs. Dockatot vs. Snuggle Me Organic, The Stork List (July 27, 2017) (last updated July 1, 2024) (attached as Exhibit 8 to CCX-2)).[12]

Kish noted that a commenter to the review had safety concerns about the Podster, prompting Kish to opine that "Even a consumer who was originally concerned about the safety of the Podster as a co-sleeper could still be influenced to disregard those warning messages based on this online review," and noted that Respondent had not commented on the article. CCX-2, at 45. However, on cross-examination, she agreed that she had no knowledge of whether consumers in fact believed that the Podster would enable safe bed sharing or that its design would prevent overlay (a person sharing the bed who moves on top of the infant during sleep). Tr. Vol. II, at 58-60.

She also acknowledged that a source she had relied upon for information about bed sharing hazards cited overlay in an adult bed as the most common factor involved in bed sharing deaths, being present in 78%of such deaths. Tr. Vol. II, at 61. Overlay was a factor even if no other product was present in the bed where the death occurred. Tr. Vol. II, at 61. The Commission's PSA for the Podsters, which Kish supervised, noted that consumers would likely turn to other unsafe products if the Podsters were recalled. Tr. Vol. II, at 63-64; JX-34.

Kish also discussed the influence of online forums and product reviews. She cites BabyCenter.com—which claims to be "the world's number one digital parenting resource,

[11] The Web search retrieval is attached as Exhibit 7 to CCX-2.

[12] The link provided in Kish's testimony no longer retrieved the article, which is available at: https://www.thestorklist.com/leachco-podster-vs-boppy-lounger-vs-dockatot-vs-snuggle-organic/.

reaching millions of new and expectant parents monthly"—as a self-professed "*professionally-moderated* community" of four million U.S. members which showed 58 "hits" in a search performed for "Podster sleep." CCX-2, at 45 (emphasis in testimony).

One commenter admitted awareness of the warnings against using the Podster for sleep but were persuaded to disregard the warnings by the views of other consumers' experiences in "thousands of reviews" on Amazon. CCX-2, at 47-48; CCX-2, Fig. 20. Other consumers also recommended the Podster for infant sleep, which Kish cited as "additional examples of social influencing that could lead consumers looking to purchase the Podster as an infant sleeper to disregard the warnings on the Podster advising not to use it for sleep." CCX-2, at 50.

Kish said the outlook was similar at another web forum, "What to Expect," which claims to be "the world's best known, most trusted pregnancy and parenting brand." CCX-2, at 51 (citation to website omitted). The website says that its content is "accurate, up-to-date, and continuously reviewed by the What to Expect Medical Review Board and other pregnancy and parenting health experts." *Id.*

"What to Expect" promises "*medically reviewed answers*" to questions about pregnancy and parenting. *Id.* (emphasis in Kish testimony). A post cited by Kish showed a parent who was aware of SIDS being a problem nonetheless considered using the Podster for sleep, including co-sleeping. CCX-2, at 52, Fig. 21. Kish said that the claim that posts were medically reviewed could provide a false sense of security.CCX-2, at 49

Kish said that "hundreds" of Amazon customer reviews mentioned using the Podster for sleep, and that several reviews showed that consumers were aware of safety concerns but intended to disregard those concerns in favor of improved infant sleep. CCX-2, at 52-53. Amazon is the top retailer for the Podsters, according to Respondent, and Kish noted that Respondent did not comment on any of the numerous reviews posted for its products on the platform. CCX-2, at 53.

Kish testified that "desperation for sleep often leads to unsafe behaviors," especially for new parents. CCX-2, at 54. "New parents are usually sleep-deprived and are likely to do anything to get their infant to fall and stay asleep for more than an hour." CCX-2, at 54. She cited to "abundant evidence" in the literature showing that warnings may have little effect on a tired or distracted audience." *Id.* (citation omitted). Parents may thus trade a suffocation risk for the benefit of a few hours of peaceful sleep. *Id.*

As a result of the numerous factors working against the effectiveness of the Podster's warnings, consumers would not likely be motivated to change their behavior and conform to the warnings, even if they read and understood them. CCX-2, at 55-56. Thus, she concludes that the product's warnings are deficient, but would be likely to disregard the product's warnings even if they were more effectively presented, and that it would therefore be foreseeable that consumers would misuse the Podster in a dangerous way. *Id.*

Kish said that infants at the age targeted for use by the Podster typically sleep 16 to 17 hours a day. CCX-2 at 58, *citing* Infant Sleep: What are an infant's sleep needs? Stanford

Medical Center Children's Health.[13] The nature and frequency of infant sleep and the Podster's design make it "highly likely that infants will eventually fall asleep in the product," and foreseeable that a caregiver may choose to sleep at the same time, may inadvertently fall asleep during that time, or may leave the infant unsupervised while performing other tasks. CCX-2, at 58.

It is also possible, Kish suggests, that caregivers might also use the Podster for sleep when traveling or in financial hardship because they do not have an available safe sleep product. CCX-2, at 59. Kish said that caregivers may not appreciate the risks of leaving an infant unattended in the Podster or may underestimate how advanced in infant's development is. *Id.*

Infants develop very quickly, and parents may not grasp that. Tr. Vol. II, at 24-25. She said that infants may roll over as early as two months, with 75% able to do so at four-and-a-halfmonths, and 90% within five-and-a-half months. CCX-2, at 59, citing Frankenburg, et al., "Denver II Screening Chart" (1978; updated 1990); Tr. Vol. II, at 25.

Kish said that Respondent's marketing of the product suggests that the Podster will contain and secure the infant. CCX-2, at 60. But she cites CCX-1, at pages 37-41 (Mannen's report) in asserting that the design of the product can aid an infant in rolling over even before being able to do so on a flat surface. CCX-2, at 59. And parents may become leaving the infant unsupervised because a young infant remained secure while in the product, while an older infant might not remain secure. Tr. Vol. II, at 25-26.

Co-sleeping or bed sharing with an infant is another danger Kish cited. She testified that the product's design could make it appear to be an attractive option because the product is soft, easily placed in a bed, and has raised sides and a sling design that caregivers may believe will secure an infant and act as a barrier to other persons in the bed. CCX-2, at 60. While the Podster warns against using the product for infant sleep, Kish said Respondent's description of the product and its features could reinforce the decision to use the product for sleep. *Id.*

Use in a crib is also a noted danger, Kish said, because an infant could become entrapped between the Podster and the side of the crib. CCX-2, at 62. The same problem could occur if the product is placed on a bed or a couch, where the infant could roll off and become entrapped in the environment. *Id.*

Kish said that the product design and deficient warnings could lead to an infant being left unsupervised, where they could roll into a compromised position and be unable to self-rescue, leading to suffocation, serious injury, and death within minutes. *Id.*, *citing* CCX-3 generally (Dr. Umakanth Katwa's expert report).

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[13] When tested, the website link cited in the testimony did not work. The updated link is used to reach the article is: https://www.stanfordchildrens.org/en/topic/default?id=infant-sleep-90-P02237#:~:text=Generally%2C%20newborns%20sleep%20about%208,weigh%2012%20to%2013%20pounds.

Kish is skeptical of Respondent's suggestion that caregivers could properly supervise an infant while performing other tasks, such as caring for other children or cooking. CCX-2, at 63. "Especially over extended periods of time, parents or caregivers cannot be perfectly attentive, regardless of their desire to do so." *Id.* She also said that caregivers are likely to become distracted at some point, a risk which increases as infants grow because young infants are less likely to be able to roll or move on the product, and that this may foster complacency amongst parents or caregivers. CCX-2, at 63-64.

"Multitasking" contributes to a greater risk of accidents and injuries, Kish said. CCX-2, at 64. She concluded that Respondent's marketing may give consumers a false sense of security about their ability to pay adequate attention while an infant is in the Podster. *Id.* Kish concluded, therefore, that infants were likely to be left unsupervised. Tr. Vol. II, at 37-38.

Kish testified that Respondent's customer service records showed consumers were using or contemplated using the Podster for sleep. CCX-2, at 65. She acknowledged that Respondent typically responded that the products should not be used for sleep, attaching warning labels with its responses. CCX-2, at 66. She noted that a consumer had disregarded the company's warnings that the Podster was not to be used for premature or unhealthy infants, calling the Podster a "preemie must have," and saying she used the Podster for sleep for three months before transitioning to a crib. CCX-2, at 66-67.

Kish discussed all three IDIs involving the Podster. She noted that the Alabama IDI reflected the daycare worker's ignorance of both product warnings and the daycare center's sleep policy and had both used a Podster for infant sleep and had placed the Podster in a crib. CCX-2, at 67-68 (citation to IDI omitted). The child also exceeded the recommended weight limit and was left unattended. CCX-2, at 68.

The Texas IDI involved a co-sleeping death, where the infant had been placed between her parents in a bed and appears to have rolled off the product and died. While the death was officially ruled as SUID, the report cited "[p]ositional asphyxia due to co-sleeping in an unsafe sleep environment as contributory" under the circumstances. CCX-2, at 69 (citation to IDI omitted).

The Virginia IDI also involved a child placed for sleep in a Podster, within a playpen, in a daycare center, who was left unattended. *Id.* This death was also attributed to "sudden unexpected infant death with unsafe bedding and positioning." CCX-2, at 69-70. The caregiver's husband said he and his wife had purchased a Podster for their own infant daughter on the recommendation of their pediatrician, who said they could use the product to elevate her if she had a cough or cold and had trouble breathing. CCX-2, at 70 (citation to IDI omitted).[14]

Finally, Kish noted that Leachco's own employees had either used the Podster improperly for sleep or had family members who had done so. CCX-2, at 70-71. She concluded

[14] Complaint Counsel has criticized the claim that the Podster's elevated position might help with breathing. The fact that the caregiver's husband said a pediatrician recommended the Podster is double hearsay and is not credited as evidence either that a pediatrician said this or that the Podster is helpful for infants with breathing difficulties.

based on review of all of the evidence that it was foreseeable that infants would fall asleep on the Podster and move into a compromised position; that consumers would be influenced by past behavior and would likely continue to allow infants to fall asleep and remain asleep on the Podster; that consumers receive contradictory information about infant care and that soft, cushioned products like the Podster are frequently marketed as appropriate infant sleep products; and that consumers seeking to bedshare are likely to seek out products to support that choice, and that it is foreseeable that such consumers would believe the Podster would fulfill the functions needed to do so. CCX-2, at 71.

Kish said that the only safe alternative to products like the Podster is a product, approved by the CPSC, i.e., a crib, bassinet, or play yard, with a firm, flat surface. Tr. Vol. II, at 28. On cross-examination, she acknowledged that the Commission has banned inclined infant sleep products and a certain type of infant pillows, but that the Podster is an infant lounger and does not fall within either product category. Tr. Vol. II, at 35-36.

Kish searched for "Leachco Podster" and reviewed social media posts she discovered in her search, but does not know how many consumers performed the same searches or reviewed the posts. Tr. Vol. II, at 44-45, 48. She described a "significant alarming pattern of counter-examples" showing the Posters being used for sleep, but did not define "significant alarming pattern." Tr. Vol. II, at 46. And though she testified that many consumers were influenced by social media posts, she admitted that she did not know did not know how many. Tr. Vol. II, at 46-47.

When she cited an online comment noting "thousands of reviews on Amazon" Kish did not know if there were in fact thousands of reviews of the Podsters on Amazon. Tr. Vol. II, at 55. And similar to her use of the term "alarming pattern," she did not have a fixed meaning for the terms "rife" or "prevalent," which she used to discuss the number of comments or reviews endorsing the use of the Podsters for sleep. Tr. Vol. II, at 55-56.

Kish also testified that consumers might view the product and its marketing and determine that the Podsters were safe for bed sharing or co-sleeping, but she admitted she did not have any evidence about consumer views concerning that subject. Tr. Vol. II, at 58-59. She acknowledged that 78 % of infant bed sharing deaths were caused by "overlay" by an adult occupant, with or without any other product in the bed. Tr. Vol. II, at 61.

Kish supervised the preparation of CPSC PSA No. 598.21, which determined that if the Podsters were recalled, "[c]onsumers interested in bed sharing would likely turn to products that can easily be used in bed such as baby boxes or in bed sleepers if they remain available. Alternatively, consumers may use adult side pillows or other forms of bedding to bed 8 share with their infants." Tr. Vol. II, at 64 (quoting JX-34, at 16).

The AAP, the National Institutes of Health, and the CPSC all recommend not permitting an infant to remain sleeping in any environment other than on an approved sleep product with nothing else in the product, though Kish agreed that "perfect parental supervision is not possible," and the recommendations do not assume it. Tr. Vol. II, at 79-83; RX-2; RX-3; RX-37.

Kish criticized Leachco for not noting that consumers were using the Podsters for sleeping and not taking a more proactive approach to remind them that this use was not consistent with the product's intended use. Tr. Vol. II, at 92-93. She said that in her opinion, if Respondent had done this, fewer consumers would use the Podsters for sleep. Tr. Vol. II, at 93.

In conclusion, Kish said it was her belief that there is no such thing as a safe infant lounging pillow. Tr. Vol. II, at 106.

4. Complaint Counsel Calls Jamie Leach, the Creative Force Behind Respondent, as an Adverse Witness.[15]

Leach is Respondent's vice president, secretary, treasurer, and chief of product development. Tr. Vol. II, at 110-11. Her husband, Clyde, is the president and chief executive officer of the company, and her son, Alex, is its chief operating officer. Tr. Vol. II, at 111. Leach has designed all of Leachco's products, including the Podsters. Tr. Vol. II, at 111-12.

Leach was trained and worked as a nurse but has not practiced in more than 25 years. Tr. Vol. II, at 112. She designed the Podster based, in part, on her experience as a nurse, mother, and grandmother. Tr. Vol. II, at 112-13. She believes that elevating an infant can be helpful with breathing and digestion. Tr. Vol. II, at 118. *See also* JX-30 (Podster Product description from Respondent's website.)

While she believes this is "common knowledge" and said she had heard doctors advise parents to elevate their child slightly, she could not specifically cite to any literature or other professional material supporting the practice. Tr. Vol. II, at 117-18. She also believes the Podster to be a safe product. Tr. Vol. II, at 119. She stood by communications made by Respondent reassuring the public that the product was safe and disputing the CPSC's allegations. Tr. Vol. II, at 121-23; CCX-11; JX-32.

However, Leach also acknowledged that in a deposition, her daughter, Mabry Ballard, had testified that she (Ballard) had used a Podster improperly, allowing her child to sleep in in it, including bed sharing with her, and that she had placed the Podster on a surface other than the floor or ground. Tr. Vol. II, at 124-29; CCX-42, at 5. Leach also said that she personally had only used the Podster as a pet bed for her dogs, noting that her children were too old. Tr. Vol. II, at 125-26.

Leach was also questioned about Tonya Barrett, Respondent's compliance coordinator, and Barrett's awareness that Barrett's own daughter-in-law had used the Podster as a sleep product for Barrett's granddaughter. Tr. Vol. II, at 130-34. As she testified at her deposition, Barrett had a conversation with her daughter-in-law about the Podster's warning against using it for infant sleep, and when her daughter-in-law told her she had used it for that purpose a second time, Barrett took the product from her daughter-in-law and refused to let her grandchild use it. Tr. Vol. II, at 133-34; CCX-43, at 7, 10-15.

[15] Respondent deferred examination of Leach until its case in chief and then elected not to examine her. There was therefore no cross-examination of the witness at the hearing.

Questioned about testing for the Podsters, Leach admitted that her testing of the Podsters was limited to using a doll with a prototype to estimate the proper size and to assess visually how the products would be used. Tr. Vol. II, at 134-37. While she agreed it was important to perform required tests, and that the company had a third-party contractor perform such tests for phthalates and sharp parts, Respondent did not contract for or perform any tests for firmness, airflow, or suffocation risks. Tr. Vol. II, at 134, 141.

Respondent also did not conduct further testing after it learned of the death reported in the Alabama IDI or after the other deaths where the product had been present. Tr. Vol. II, at 143-47. Nor did the company conduct its own investigation of the incidents in response to the IDIs. *Id.*[16]

5. Dr. Umakanth Katwa Testifies to Infant Physiology, Breathing, and Sleep Effects Based on Mannen and Kish's Projections.

Dr. Umakanth Katwa is a medical doctor, board-certified pediatric pulmonologist and sleep specialist. CCX-3, at 5. He was tendered and accepted as an expert medical witness for the Commission. As with the other expert witnesses, Katwa submitted a report as his testimony and was permitted to amplify the report on direct examination (although he did not do so) and was subject to cross-examination and re-direct examination on his report.

Katwa based his analysis on "the current literature on infant breathing, infant breathing physiology, infant sleep maturation, breathing in the prone position, and neck and trunk flexion," as well as the AAP safe sleep guidelines and recommendations, Mannen's data from her tests of the Podsters, Kish's testimony, the IDIs and PSAs for the Podster, and samples of the Podster standard and plush models. CCX-3, at 5.

Katwa said that that there are approximately 3,500 sleep-related infant deaths in the Unites States each year. *Id.* These include both SUID deaths and those resulting from accidental strangulation and suffocation in bed. *Id.* He cited to the AAP's safe sleep recommendations (sleep on a firm, non-inclined sleep surface in the supine position, share a room but not a bed with the infant, and avoid soft bedding and overheating. CCX-3, at 5-6.

[16] Leach was questioned about Respondent's allegations that the CPSC's proceeding against the Podsters had financially harmed the company. At the hearing, the relevance of this line of inquiry was questioned. Tr. Vol. II, 154. Complaint Counsel asserted that the questioning might be relevant if its relief was granted, and Respondent's finances would need to be considered in determining how compliance costs should be apportioned. *Id.* A ruling on this question, and on the deposition testimony of Jamie Leach, was deferred. Tr. Vol. II, 158. Complaint Counsel subsequently withdrew its motion to enter the Leach's deposition testimony into the record. Tr. Vol. IV, at 4. Respondent also submitted financial records as a contingency for the same purpose. *See* RX-38; RX-39 (unredacted financial records); RX 40, 41 (redacted versions). Because this proceeding has not granted the relief sought, the evidence is not relevant and has not been considered for any other purpose. However, if the decision in this proceeding is appealed, the evidence could be considered by the Commission or on remand.

Katwa said that the three primary risk factors cited in medical literature for accidental infant sleep deaths are (i) intrinsic vulnerability, "such as impaired arousal or rescue response during sleep," (2) exposure to unsafe sleep environments, contrary to the AAP guidelines, and (3) the infant's stage of development. CCX-3, 6.

Katwa said that the first six months of life is a critical stage for infant development. *Id.* Their lungs are immature, as is control over breathing. *Id.* Infants experience frequent breathing pauses ("central apnea") during sleep at this stage. *Id.* During this time, infants have "suboptimal and inefficient breathing mechanics" and respond abnormally to low oxygen and elevated CO_2 levels. *Id.*

Infant lungs are very small and less flexible than adult lungs and have low capacity and breathing reserve. *Id.* Katwa said that even brief pauses in respiration "can result in a rapid and problematic drop in oxygen levels." *Id.* Infant physiology is also different at this stage. Katwa said that an infant's chest cage is bell-shaped, highly flexible, and mostly cartilaginous, and that the shape of the chest and diaphragm do not allow big breaths. *Id.* *See also* CCX-3, at 8, Fig. 1 (diagram of infant physiology and breathing mechanics). This places infants at a mechanical disadvantage, and results in shallow and rapid breaths compared to older children. CCX-3, at 6-7.

Katwa said that infants must breathe faster to maintain their oxygen level. CCX-3, at 7. Unlike adults, infant breathing is mainly abdominal, and controlled by the diaphragm, the dome-shaped muscle at the base of the lungs. *Id.* Trunk flexion, sleeping in a slouched position, or other pressure on the diaphragm will impede breathing movement and result in shallow breathing and low oxygen levels. *Id.* This immaturity in breathing physiology can extend up to six months of age and is exacerbated in infants born prematurely. *Id*. The resultant breathing pattern manifests as a repetitive cycle of brief apnea followed by normal breathing and is predominantly seen during rapid-eye-movement ("REM"), or "dream," sleep. *Id.*

The cycle leads to frequent drops in oxygen levels, which are often asymptomatic and difficult to diagnose. *Id.* The conditions are worsened when the infant is exposed to low oxygen levels (hypoxemia) and can be aggravated further by neck flexion. *Id.* Because infants are obligatory nasal breathers, nasal blockage can lead to apnea and hypoxemia, even if the mouth is not also obstructed, because infants cannot transition from nose to mouth breathing. *Id.*

Katwa testified that the immature breathing pattern found in infants tends to worsen during the first four to six weeks of life and then resolves slowly over the next three to four months. CCX-3, at 8. The periodic breathing cycle tends to get worse when exposed to lower oxygen levels and can lead to respiratory depression, "manifested as reduced breathing effort and a cessation of breathing." *Id.* Hypoxemia can worsen where neck flexion results in airway compression, leading to obstructed breathing. *Id.*

Infants placed in a stressful or unsafe sleep environment are at a "high risk of life-threatening events or sudden unexpected infant death." *Id.* An inclined environment and/or sleeping on a soft surface can compromise breathing by neck or trunk flexion. *Id.* Sleep studies show that during their first six months of life, infants may experience the periodic breathing

cycle up to five percent of the time, resulting in dips in oxygen levels. CCX-3, at 9, Fig. 2. The cycle may worsen if the infant is exposed to hypoxic conditions but improves with development as infant brain and arousal mechanisms mature and core muscle strength improves. *Id.*

Katwa said that the position of an infant's neck during breathing significantly affects airway stability and patency (the ability to remain open to sustain airflow and support breathing). CCX-3, at 10. Neck flexion greater than 30 degrees can "easily" narrow or collapse the airway, and at 45 degrees of flexion, the airway may be occluded completely. *Id.*

Katwa said when the neck is flexed, the muscles of the airway tend to relax and then collapse and occlude. *Id.* This leads to a reduction of the volume of air the infant can inhale and exhale. *Id.* With neck flexion greater than 45 degrees, the airway can be completely obstructed, and airflow may cease, even if the infant is trying to breathe. *Id.* The diaphragm is unable to generate enough force to draw air in through the narrowed airway. CCX-3, at 10-11. As more effort is required, the diaphragm tires and gives up, which may cause breathing to cease. CCX-3, at 11. Because infants' airways are very small, they can easily collapse and be blocked, and neck flexion is known to make the airway more susceptible to this collapse. *Id.*

The inability of an infant to exert sufficient inspiratory effort when the neck is flexed while sleeping can lead to prolonged airway obstruction and apnea, progressive and severe hypoxemia, a drop in heart rate and, ultimately, cardiorespiratory arrest and death. *Id.* Thus, Katwa says it is "extremely critical" that infants maintain a neutral sleep position on a flat, firm sleep surface, consistent with the AAP guidelines. *Id.*

An infant's response to low oxygen levels is different from the response of older children or adults. CCX-3, at 13. While adults can maintain increased breathing speed and volume in response to low oxygen availability (such as that found at higher altitudes), infants experience respiratory fatigue from the increased work required to breathe, and the persistent hypoxemia they experience leads to depression of the breathing area of the brain, respiratory depression, and, eventually, a cessation of respiration and death. *Id.*

Katwa said that newborn infants spend most of their time sleeping—about 16-18 hours per day. CCX-3, at 14. In the first two to three months of life, infants sleep in short two- to three-hour sessions, and do not establish a full day/night sleeping pattern until they are five or six months old. *Id.* At about three to four months, infants begin to sleep longer at night and will take two to four short naps during the daytime. *Id.* Once the day/night pattern begins at six months, infants may sleep eight to 12 hours at night and take two or three short (one- to two-hour) naps during the day. *Id.*

Young infants tend to fall asleep after feeding, rocking, bathing, or crying, and can fall asleep at any time of day. *Id.* Katwa said that infants enter REM sleep during naps, which is not typical in older children or adults, who experience REM sleep only at night. *Id.* Further, the time infants spend in REM sleep may be 50% of their time asleep, whereas adults spend on 20 % of their sleep time at night in REM sleep. *Id.* Katwa said that infants' respiratory muscles tend to relax during REM sleep, resulting in much more shallow breathing than when they are awake or in non-REM sleep. *Id.* During REM sleep, infants are at their highest physiological risk for

respiratory compromise. *Id.* Maturation of sleep and breathing is further delayed in premature infants. *Id.*

Katwa testified about the protective arousal response to stimuli in infants. CCX-3, at 15. This state of heightened alertness or activation in the brain may awaken a sleeping person and can be measured by increased brain activity, heart rate, breathing rate, and changes in blood pressure. *Id.* The response may be triggered by light, sound, touch, and movement. *Id.* Arousal may also be triggered by a drop in oxygen levels, increased CO_2, nasal obstruction, and increased breathing effort. In those circumstances, infants are triggered to "self-rescue" by taking larger recovery breaths and moving into a less stressful position. *Id.*

The arousal response may be adversely affected by changes in body temperature, persistently low oxygen or elevated CO_2levels, or reduced blood flow to the brain. Reduced blood flow or oxygen will dampen the neural response in the brain, and the rescue mechanism will be affected. *Id.*

When an infant turns on a soft, inclined sleep surface, nasal passages may be blocked, leading to reduced breathing and oxygen. *Id.* The infant may rebreathe its own air, resulting in an increased body temperature and a progressive decrease in oxygen and increase in CO_2 levels. *Id.* Because its arousal response may be dampened by these conditions, an infant may not be able to wake up, cry, or move to an improved position. *Id.* In that state, infants are only able to achieve a full arousal response to an airway obstruction about 20% of the time, compared to about 50% of the time in children, and more than 80% in adults. *Id.*

While infants are much smaller than adults, and the volume of air they require is therefore smaller, their metabolic demands are much greater than adults', and they thus need a constant supply of oxygen. CCX-3, at 16. Typically, an 11–13-pound infant will require two liters of air per minute to maintain stable oxygen and CO_2levels. *Id.* An infant unable to breathe because of an obstructed airway will quickly develop hypoxemia and elevated CO_2 levels. *Id.*

If this lasts for an extended period, Katwa said the infant's body may attempt to provide more oxygen to tissue by increasing respiratory rate and depth (hyperventilation). *Id.* The infant's heart rate may increase, and increased breathing effort may be required. *Id.* If the responses are inadequate, the infant may suffer respiratory muscle fatigue, respiratory failure, potentially life-threatening hypoxemia, and an inability to wake up and self-rescue. *Id.*

Katwa then evaluated and provided his opinion about the risk of injury from use of the Podster. He said that the product's surface is soft and overly compressible and does not meet the AAP standards for a flat, firm sleep surface. CCX-3, at 17.[17] An infant on such a product, which

[17] Some of Katwa's testimony was excluded, as noted above, by an August 2, 2023, order because he is not a human factors expert. Order Granting in Part and Denying in Part Respondent's Motion to Exclude the Expert Testimony Proffered by the Consumer Product Safety Commission, Aug. 2, 2023 (hereinafter "Aug. 2, 2023, Preh'g Order"), at 6-7. However, Katwa stated that he relied on Mannen's data, and his testimony essentially assumes the at at

(continued . . .)

Katwa likened to an "inclined sleep product," who moves from a supine to a prone or side-lying position, and who is thus entrapped against the product's walls, may suffocate from a blockage of the nose and mouth. *Id.* Reduced airflow and prolonged rebreathing leads to increased hypoxemia, elevated CO_2, "reduced oxygenation to the brain, unconsciousness, and ultimately serious neurological injury and/or death. CCX-3, at 17-18.

Katwa reviewed and accepted Mannen's conclusions about the incline angle of the Podster, head/neck and trunk flexion, the firmness of the Podster's surface , the product's shape, and airflow changes in the prone position. CCX-3, 18-19. Katwa said that the incline found by Mannen in her study would exceed 10 degrees and would thus increase the risk of muscle fatigue and shallow breathing. Accepting the potential that an infant would move into a "fetal tuck" position, Katwa said that increased pressure on the abdominal cavity in that position would affect the movement of the diaphragm, possibly leading to increased breathing work, muscle fatigue, reduced breathing movements, and respiratory arrest. CCX-3, 18.

Accepting Mannen's conclusions about head and trunk flexion, Katwa said the degree of flexion facilitated by the Podster would also result in increased airway compression and abdominal pressure, which could impede breathing movements of the diaphragm and could cause hypoxemia and increased levels of CO_2. CCX-3, at 18-19.

Katwa reiterated that soft sleep surfaces are known to increase the risk for suffocation and sudden infant deaths. CCX-3, at 19. Citing medical references, Katwa noted that 14% of SUID resulted from suffocation, including from soft bedding, blankets, or pillows, or from sleeping on couch cushions or adult mattresses. *Id.* He also concluded that if an infant moved into a prone position on the Podster, and if Mannen's airflow calculations were correct, the resultant rebreathing of increasingly concentrated CO_2 could result in unconsciousness and neurological damage or death. CCX-3, at 20.

Based on Mannen's data and applying his own expertise to her conclusions about positioning on the product and its physiological effect on infants placed on it, Katwa opined that "the Podster is a dangerous product in which infants can die of positional asphyxia and suffocation." CCX-3, at 21. His conclusion restated the findings he made concerning increased intraabdominal pressure, the effect of that pressure on the diaphragm and breathing mechanics, respiratory muscle fatigue, and a resulting progressive hypoxemia and high carbon dioxide levels. CCX-3, at 21-22.[18]

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[17] (. . . continued)
conditions that she found would be likely to develop. Thus, his testimony as to the effect of the Podster properly relied on competent expert testimony on human factors and is recited here. However, his opinion about the likelihood of movement within the product and his endorsement of the scientific validity of Mannen's tools and methods is outside his area of expertise and has not been considered.

[18] The remainder of Section VI of Katwa's testimony essentially repeats conclusions he has already stated, entwined with an endorsement of Mannen's conclusions, which are beyond his area of expertise. They were thus reviewed but are not summarized in this opinion. *See* CCX-3, at 23-26.

Finally, Katwa reviewed the three IDIs prepared by the CPSC. The IDI noted that a four-month-old infant was placed in a Podster at a day care center with a bottle and left unattended for an unspecified amount of time. CCX-3, at 26. The day care staff member said that the infant was found unresponsive and face down. The child was transported to a hospital and placed on a respirator but could not be revived. *Id.*

Katwa found that the results of the medical examination of the deceased infant in the Alabama IDI showed spinal cord neuron necrosis and blood pooling in brain neurons consistent with brain death. CCX-3, at 27. He concluded that the findings showing "focal bilateral purulent mucus plugging of the small airways in the lung" and large bowel infarction were most likely caused by prolonged hypoxemia. *Id.*

If the infant was able to move to a prone position while left unattended and was unable to self-rescue, the resulting circumstances could have resulted in suffocation, progressive hypoxemia, brain damage, and death. *Id.*[19]

In his review of the Texas IDI, Katwa noted that the medical examiner could not conclusively establish a cause of death, but stated, "[p]ositional asphyxia due to co-sleeping in an unsafe environment" could not be excluded due to the circumstances, which included the infant placed to sleep on a Podster between both of her parents on an adult bed. CCX-3, at 27. Katwa concluded that the unsafe sleep environment led to prolonged hypoxemia, suffocation, and death. *Id.*

In the Virginia IDI, the infant was left unattended in a Podster placed inside a crib, along with a nursing blanket. CCX-3, at 28. The caregiver's husband testified that when he checked on the girl, she was on her side with her face against the Podster. *Id.* She was limp, pale and not breathing. *Id.* Attempts to revive her were unsuccessful. *Id.* The medical examiner attributed the death to "Sudden unexpected death with unsafe bedding and positioning." *Id.* Katwa concluded from the IDI that suffocation can happen if the infant is in a side-lying position. *Id.*

Katwa concluded by summarizing his testimony and concluding that in his opinion the Podster is "a dangerous and unsafe surface for infants." CCX-3, at 30.[20] On cross-examination, though, Katwa acknowledged that the guidelines for safe sleep apply to *all* products that place infants in an inclined position, and that they recommend removing the infant from any such product if the infant falls asleep, when it is safe and practicable to do so. Tr. Vol. III, at 15; RX-37 (AAP Guidelines).

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[19] Katwa's conclusion about the "dangerous design" of the Podster limiting the child's ability to self-rescue is outside the scope of his expertise and is excluded by the August 2 order. However, his medical opinion about the cause of death, assuming facts reasonably derived from the evidence, and his reliance on Mannen's competent opinion about the Podster's design, is accepted, although its weight and validity are heavily dependent on the validity of the evidence upon which he relies.

[20] Katwa's section VIII, "Marketing Disinformation," is outside the scope of his expertise and has not been considered.

6. Respondent's Expert Peggy Shibata Criticizes Complaint Counsel's Expert Witness Testimony and Notes the Podster's Characteristics Are Not Unique Amongst Infant Products Not Designed for Sleep

Respondent tendered Peggy Shibata as an expert in biomechanics. RX-1, at 4. Shibata is a professional engineer with masters' degrees in both biomechanical and mechanical engineering. *Id.*

After summarizing the basic procedural posture of the case, Shibata reviewed the three IDIs for the fatal incidents where a Podster was present. In the Alabama IDI, Shibata provided an overview of the fatal incident, where a four-month-old boy was placed with a bottle on a Podster in a crib and left unattended. RX-1, at 6. A daycare employee found the infant "making a gurgling sound" but otherwise "purple/blue, limp, lifeless and unresponsive." *Id.*

Reports about how the infant was positioned when he was found were inconsistent, with the daycare incident report stating that he was found face-down on the product, and the medical examiner's report saying he was found lying on his back. The Jefferson County Medical Examiner found the cause of death to be complications of asphyxia. *Id.* The medical examiner's report also mentioned that there was a tag on the green Leachco Podster lounger that read: "***Warning; do not allow infant to sleep in this product; never leave infant unattended***." *Id.*

The Alabama Department of Human Resources cited deficiencies at the daycare center, including allowing a child to sleep in a positioning device without documentation from a physician permitting this, leaving a child in a crib with a pacifier with a small stuffed animal attached to it, leaving a teddy bear in the crib, and an improper (16-17:2) ratio of infants to teachers. *Id.*

In the Texas IDI, Shibata noted that the 17-day old female infant was found unresponsive after sleeping in bed with her parents. *Id*. The child had been placed face-up on a Podster for sleep, with a blanket on the lower half of her body, in between her parents in a queen-sized bed. *Id.* The mother had fed her daughter approximately three ounces of milk at 2 A.M. before putting her back to sleep. *Id.* When the mother next awoke, her daughter was no longer on the Podster. RX-1, at 7. The husband then awoke and found his daughter lying face-up and unresponsive in the bed. *Id.*

The medical examiner ruled the cause of death as "sudden unexpected death in infancy" but said that positional asphyxia from sleeping in an unsafe environment could not be ruled out. RX-1, at 6. A police report said that the child was found with small amounts of blood coming from her mouth and nose, but the parents could not be sure whether the blood was present before or after the father began trying to resuscitate his daughter by CPR. RX-1, at 7. Prior to the incident, the infant had sometimes made gasping sounds while breathing and had been scheduled to see her doctor on January 29, 2018—two days after the fatal incident. *Id.*

The Virginia IDI cited the Chief Medical Examiner's report of autopsy after an infant was found deceased after her caregiver had placed her to sleep on her back on a Podster placed inside a playpen.[21] *Id.* After 45 minutes, the caregiver's husband checked on the girl and found her on her side and unresponsive on the Podster. *Id.* He had picked her up to reposition her and found her pale, limp and not breathing. *Id.*

Cause of death was listed by the Chief Medical Examiner as "Sudden unexpected infant death with unsafe bedding and positioning." *Id.* The manner of death was undetermined. *Id.*

The death occurred at an in-home daycare facility, and four other children were in the home at the time of the incident. *Id.* The caregiver stated that she had propped the infant up on the Podster for elevation because she was extremely congested. *Id.*

After summarizing the IDIs, Shibata outlined the allegations made in the Complaint against the Podsters. RX-1, at 7-8. Noting that the Complaint acknowledged that the Podster has never been advertised for use as a sleep product, and that warnings accompanying the product caution against using it for sleep, Shibata asserted that there were no mandatory regulations and no voluntary consensus standard relevant to the Podsters' design. RX-1, at 8. She noted the warnings included with the Podster, and the caution that failure to use the product properly could result in serious injury or death. *Id.*

Shibata then addressed the three PSAs that CPSC conducted related to the Podsters. *Id.* Shibata cited the deposition of Hope Nesteruk, one of the CPSC's investigators, about the PSAs, which considered the IDIs for the three incidents, along with Respondent's warnings, marketing and advertising materials, packaging, instructions, and the products themselves. RX-1, at 8-9, *citing* Hope Nesteruk Dep. March 15, 2023, at 40.

Shibata cited the human factors allegations made by the CPSC against the Podsters, including that its design promotes misuse, that the products' warnings are ineffective, and that infant sleeping is therefore foreseeable. RX-1, at 9.

Shibata said the CPSC has noted in developing standards that some hazards cannot be "designed out" but must be addressed with warnings:

> [B]ecause many deaths and non-fatal incidents involve suffocation due to caregivers and parents using bedding materials (such as pillows and blankets) that are not specified by the manufacturer, and because these incidents cannot be addressed by the design of the bassinet or cradle, it is imperative to improve the warning labels regarding padding and soft bedding in the standard.

Id., *quoting* Safety Standard for Bassinets and Cradles: Notice of Proposed Rulemaking, 75 Fed. Reg. 22303, 22307 (April 28, 2010).

[21] Shibata's report apparently transposed the age of the infant from the Texas IDI, stating that the girl in the Virginia report was 17 days old. She was in fact three months old and weighed 14 pounds. JX-12(a), at 2.

One of the CPSC's PSAs cited by Shibata says that it is foreseeable that parents will improperly use adult pillows as infant sleeping areas, and Shibata argues that the Podster differentiates itself by its specific warnings and "improves the situation." RX-1, at 9.

Shibata asserted that there is "no basis" for the CPSC's claim that the design of the Podsters promotes misuse. *Id.* "There have been no characteristics that are unique to the Podster (compared to other infant products) that have been specifically identified as leading to misuse by caregivers." *Id.* She said that "the CPSC is surely aware of numerous examples of other products that are 'simple to use, likely to be used frequently, and [do] not appear [to be] dangerous,' and that are available to the public. *Id.*, *citing* Zachary Foster Dep., March 8, 2023.

In a November 2022 report on deaths associated with nursery products, Shibata said the CPSC concluded that "most of the deaths" associated with cribs, play yards, bassinets, and other infant products are related to misuse, such as the introduction of soft bedding, placement near hazardous environments, or improper assembly or use. RX-1, at 1, *citing* U.S. CPSC, "Injuries and Deaths Associated with Nursery Products Among Children Younger than Age Five," November 2022.

Shibata said that consumer misuse of infant products is not uncommon, and that "[n]o studies or literature show that the Podster is uniquely susceptible to misuse. RX-1, at 10. Noting that any product safety evaluation requires a balance of risk and utility, Shibata cited to the positive features of the Podsters and argued that if the Podster were not available, "Consumers may resort to using less-safe alternatives for lounging, including the floor, couches or elevated surfaces without sidewalls, or unshaped adult pillows, blankets, or bedding." *Id*.

Noting the common characteristics of other products, Shibata said that there is no support for the theory "that the Podster is uniquely more likely to be misused than any other infant product." *Id.* She claimed that it is known that in the safety community that "it is not possible to attain a level of zero risk," and that the European Union has published risk assessment guidelines to determine whether some remedial action for consumer products is recommended. RX-1, at 11; RX-1, Table 3 ("EU RAPEX Risk Estimation Matrix"). Shibata says that the CPSC has provided no basis for determining that the risk level associated with the Podsters is "objectively unacceptable," and that other infant products are associated with a greater number of incidents than the Podster. RX-1, at 11.

Shibata then discussed the product warnings, both on the product packaging and the product itself. She says that the warnings are consistent with principles for effective warnings and that Respondent's website information is consistent with and supports the product warnings. RX-1, at 12-14. Again, she grounded her opinion on the lack of foundation for the claim that the Podsters "*uniquely* will lead to caregivers ignoring the provided warnings and instructions. RX-1, at 14 (emphasis added). She criticized the opinions produced in the PSAs as lacking scientific foundation for the claim that the Podster's warnings are ineffective. RX-1, at 14.

Numerous infant products not intended for sleep rely on warnings and instructions to caregivers, including strollers, car seats, bouncers and swings. *Id.* Shibata cited to a publication produced for CPSC staff acknowledging that parents may be aware of product warnings but fail

to follow them due to compliance costs or conflicting information from trusted sources. *Id. citing* Fors Marsh Group, "Consumer Product Safety Commission (CPSC): Caregiver Perceptions and Reactions to Safety Messaging Final Report," August 12, 2019.[22]

Turning to Mannen's opinion on biomechanics, Shibata criticized the CPSC's reliance on Mannen's study of infant sleep products in preparing its PSAs, because the Podster is not such a product. RX-1, at 15. She said that the structure and use of infant sleep products is different and that drawing conclusions about the Podster from such products is inappropriate because there is no foundation supporting the Commission's application of "conclusions from one product category . . . to another, distinctly different, product category." *Id.*

She also said that a PSA evaluating the Podster improperly considered an infant positioned prone on the Podster, contrary to its utility and intended use and opposite to its main intuitive use. *Id.* Further, Shibata criticized the PSA for its reliance on Mannen's conclusions about incline angles in her 2019 study of infant sleep products, without noting the distinctions or similarities between the Podsters and those products. RX-1, at 16. Shibata further said that Mannen's conclusions about infant muscle fatigue and the ability to roll were based on evaluations of infants in different positions and on a flat surface, not on the Podster. RX-1, at 17.

Mannen's simplified sagittal plane testing device was not validated to ensure it accurately measured the joint angles of an infant, Shibata said. *Id.* Further, the use of the device and its conclusions were based on research studying adults in a normal seated position. RX-1, 18. She characterizes Mannen's relating the ability and mechanics of infants rolling on a flat surface to the mechanics of moving on the Podster as "speculative." Tr. Vol. IV, at 19. She also said that conclusions reached in two of the CPSC's PSAs were contradictory in their explanations of infant movement on the Podster, with one PSA claiming the Podster limited an infant's ability to move on the Podster and the other claiming its design facilitated unsafe movement. Tr. Vol. IV, at 19-20.

Shibata also criticized Mannen's simulation of head/neck and trunk flexion, faulting her techniques and assumptions about infant movement on the Podster as well as her use of a device that Shibata claimed could not accurately represent the complex cartilage, muscular, and skeletal structure of an infant's body. Tr. Vol. IV, at 20. She again criticized Mannen's reliance on study results produced in observation of adults in seated or slouched positions to conclude that infants would experience respiratory compromise in the Podsters. Tr. Vol. IV, at 20-21.

Both a CPSC PSA performed for the Podster and Mannen's research cited in the PSA were also challenged by Shibata concerning their assertions about the "heavy plush" material covering the Podster. Tr. Vol. IV, at 21. Shibata suggested that the plush material could impede an infant moving into the prone position and argued that if the material would make it difficult

[22] Shibata cites this as a CPSC publication, but the cover of the report states, "This report was prepared by Fors Marsh Group for CPSC staff. It has not been reviewed or approved by, and does not necessarily represent the views of, the Commission." Kish relied on this study and a subsequent 2021 Fors Marsh Group study in her testimony. *See* Tr. Vol. II, at 31.

for an infant to correct its motion from a prone position to a supine position, it could also make it difficult for an infant to move to the prone position from the intended supine position. *Id.*

Citing a German study and a standard developed in Australia and New Zealand referencing the study and referred to in the CPSC's PSA, Shibata questioned the PSAs reliance on the study to characterize the Podster as too soft. Tr. Vol. IV, at 20-21, *citing* Martin Schlaud, et al, The German case control scene investigation study on SIDS: epidemiological approach and main results, Springer-Verlag (2009),[23] and RX-1, Appendix B, 3.001, 7, 12. Shibata said that the Schlaud study found differences in firmness in the tested products were no longer statistically significant in relation to SIDS, after accounting for differences in infant age, socioeconomic status, nationality, and other factors. *Id.*

Additionally, the flat disk used in the CPSC's tests for firmness was intended to be used on flat surfaces, so that use on products with a curved surface, such as the Podster, the product would automatically fail the test. Tr. Vol. IV, at 22. Further, Shibata said that the PSA failed to note questions raised in the CPSC's airflow studies about the effect of minor airflow changes on infant breathing abilities. Tr. Vol. IV, at 22-23. She also says that Mannen did not evaluate the effect of plush material on infant breathing in any detail. Tr. Vol. IV, at 23.

Finally, Shibata took issue with Mannen's conclusions about head rotation and rebreathing, based on the shape of the Podster, especially her conclusion that a head rotation of 120 degrees could be attained by an appropriately aged infant in the Podster. *Id.* A paper referenced by Mannen observed passive range of motion——i.e., the researchers manipulated the infant's head to determine the range, rather than observing active range of motion attained during natural movement by the infants. *Id.*¸ *citing* Anna Maria Öhman & Eva Beckung, Reference Values for Range of Motion and Muscle Function of the Neck in Infants, 20 Pediatric Physical Therapy 53, 53-58 (2008). Shibata also noted that the distance from the sides of the Podster attained in Mannen's 2022 study of infant pillows was more than twice the "cautionary" distance she established for movements from the supine and "worst case" head positions. Tr. Vol. IV, 24.

Complaint Counsel's brief cross-examination confirmed that all the materials Shibata deemed relevant to her report were referenced in Appendix B to her report. Tr. Vol. IV, at 23-24. After reading an excerpt from a workers' compensation decision in which the judge was critical of her testimony in another case, Complaint Counsel prompted an admission that she had not received or studied an actual sample of the Podster in preparing her report. Tr. Vol. IV, at 26-27.

Complaint Counsel questioned whether a caregiver could provide "constant adult supervision" of an infant in the Podster while performing other tasks. Tr. Vol. IV, at 29-31. Defining "constant adult supervision" as having an adult available, in the same room, while the product was being used, Shibata insisted this was possible. Tr. Vol. IV, at 29-31, 34-36. Shibata did agree that caregivers would not necessarily choose an unsafe product or surface to place their infants if the Podster was unavailable, acknowledging that CPSC-approved infant products might also be used. Tr. Vol. IV, at 34-36.

[23] The article was admitted as CCX-60.

Finally, Shibata acknowledged that she had not herself performed any tests on the Podsters. Tr. Vol. IV, at 41. She thus had no data or direct evidence gained from observing live infants on the Podster, or measuring its firmness, incline, airflow permeability, carbon dioxide, or any medical issues. Tr. Vol. IV, at 41-42.

II. Governing Law

A. The CPSC's Authority

The Commission is an independent regulatory agency that administers and enforces the CPSA. 15 U.S.C. § 2053. *See also generally* 15 U.S.C. §§ 2051–2089 (all statutes enacted as part of the CPSA). A primary purpose of the CPSA is "to protect the public against unreasonable risks of injury associated with consumer products." 15 U.S.C. § 2051(b)(1).[24] *See also* H.R. Rep. No. 92–1153 at 33 (1972); S. Rep. No. 92–749 at 14–15 (1972).

The Commission is authorized to "promulgate consumer product safety standards" establishing performance or warning requirements for consumer products, as well as to ban hazardous products altogether 15 U.S.C. §§ 2056(a), 2057. The Commission may ban a hazardous product if:

> (1) a consumer product is being, or will be, distributed in commerce and such consumer product presents an unreasonable risk of injury; and
> (2) no feasible consumer product safety standard under this chapter would adequately protect the public from the unreasonable risk of injury associated with such product.

[24] The legislative history of the CPSA provides some insight into Congress' understanding of the term "unreasonable risk of injury":

> It should be noted that the Commission's authority to promulgate standards under this bill is limited to instances where the hazard associated with a consumer product presents an unreasonable risk of death, injury, or serious or frequent illness. . . . Protection against unreasonable risks is central to many Federal and State safety statutes and the courts have had broad experience in interpreting the term's meaning and application. It is generally expected that the determination of unreasonable hazard will involve the Commission in balancing the probability that risk will result in harm and the gravity of such harm against the effect on the product's utility, cost, and availability to the consumer.

H.R. Rep. No. 92–1153, p. 33 (1972).

15 U.S.C. § 2057. Upon such determination, "the Commission may, in accordance with section 2058[25] of this title, promulgate a rule declaring such product a banned hazardous product." *Id.*

B. "Substantial Product Defect" under the CPSA

A substantial product hazard is "a product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public." 15 U.S.C. § 2064(a)(2). Consumer misuse of a product, and the foreseeability of such misuse, may be considered in determining whether a product is defective. *See* 16 C.F.R. § 1115.4 ("In determining whether the risk of injury associated with a product is the type of risk which will *render the product defective*, the Commission and staff will consider, as appropriate: . . . the *role of consumer misuse of the product and the foreseeability of such misuse*. . . .") (emphasis added).

The CPSC has defined "defect" in a general sense:

> At a minimum, defect includes the dictionary or commonly accepted meaning of the word. Thus, a defect is a fault, flaw, or irregularity that causes weakness, failure, or inadequacy in form or function. A defect, for example, may be the result of a manufacturing or production error; that is, the consumer product as manufactured is not in the form intended by, or fails to perform in accordance with, its design. In addition, the design of and the materials used in a consumer product may also result in a defect. Thus, a product may contain a defect even if the product is manufactured exactly in accordance with its design and specifications, if the design presents a risk of injury to the public. A design defect may also be present if the risk of injury occurs as a result of the operation or use of the product or the failure of the product to operate as intended. A defect can also occur in a product's contents, construction, finish, packaging, warnings, and/or instructions. With respect to instructions, a consumer product may contain a defect if the instructions for assembly or use could allow the product, otherwise safely designed and manufactured, to present a risk of injury.

16 C.F.R. § 1115.4.

The Commission has provided 11 factors which it considers in determining whether a defect exists:

(1) [t]he utility of the product involved;
(2) the nature of the risk of injury which the product presents;
(3) the necessity of the product;
(4) the population exposed to the product and its risk of injury;
(5) the obviousness of such risk;

[25] Section 2058 provides and elaborate, detailed procedure for the promulgation of a rule banning a hazardous product. Neither party made an issue of this in prehearing motions or during the proceeding, but this proceeding is targeted toward and would require the removal from commerce of a single product.

(6) the adequacy of warnings and instructions to mitigate such risk;
(7) the role of consumer misuse of the product and the foreseeability of such misuse;
(8) the Commission's own experience and expertise;
(9) the case law interpreting Federal and State public health and safety statutes;
(10) the case law in the area of products liability; and
(11) other factors relevant to the determination.

Id. (numbering added).

C. Burden of Proof under the Administrative Procedure Act

Under the Administrative Procedure Act ("APA") and the Commission's regulation governing administrative adjudications, Complaint Counsel have the burden of proving that the Subject Products constitute a substantial product hazard under the CPSA. 5 U.S.C. § 556(d) ("the proponent of a rule or order has the burden of proof"); 16 C.F.R. § 1025.43(b)(1) ("Complaint counsel shall have the burden of sustaining the allegations of any complaint."). In addition, the party "who is the proponent of a legal or factual proposition shall have the burden of sustaining that proposition." 16 C.F.R. § 1025.43(b)(2).

The standard of proof that a proponent of a rule or order must meet to prevail in an administrative proceeding under the APA is "preponderance of the evidence." *Steadman v. SEC*, 450 U.S. 91, 102, *reh'g denied*, 451 U.S. 933 (1981).

III. Disposition

A. Whether the Podster Has a "Product Defect" is Limited to the Question of a Design Defect.

The CPSC did not assert a manufacturing defect as grounds for relief, did not introduce any evidence related to a manufacturing defect, and has advanced no argument against such defect in the Podster line. The Complaint itself acknowledged the extensive warnings against the type of misuse upon which the Complaint rests.[26] *See* Compl., ¶¶ 14-19.

The warnings provided by Respondent with its products address directly and specifically the CPSC's concerns, as expressed in the Complaint and at hearing. A previous order in this

[26] Kish disparaged the Podster's warnings as deficient. However, she also held that no warnings would have effectively deterred consumer misuse of the Podsters. A previous order in this case held that the CPSC had not preserved a "failure to warn" defect. While Kish's allegations might have presented a basis for such a claim, her position that improved warnings would have been ineffective renders it untenable. However, Kish's assertions about the defective warnings have been considered in addressing the Commission's allegations that the propensity for misuse of the Podster, which includes the inadequacy of warnings as a deterrent to such misuse, contributes to the alleged design defect.

case precluded the CPSC from including a failure-to-warn claim. *See* Aug. 2, 2023, Prehr'g Order, at 3-4.

Thus, the only issue for decision on the question of an alleged defect is whether the design of the Podster is defective. The CPSC's regulations have provided factors that the agency may consider in determining the issue.

1. The Evidence Does Not Support a Finding that the Podsters Have a "Defect," as that Term is Commonly Understood.

The Commission has advanced its own definition of "defect," which "[a]t a minimum . . . includes the dictionary or commonly accepted meaning of the word." 16 C.F.R. § 1115.4. "Thus, a defect is a fault, flaw, or irregularity that causes weakness, failure, or inadequacy in form or function." *Id.*

The Commission does not cite a dictionary for its basic definition. However, a common dictionary definition is generally consistent, defining "defect" as "an imperfection or abnormality that impairs quality, function, or utility: SHORTCOMING, FLAW." Defect, Merriam-Webster.com, https://www.merriam-webster.com/dictionary/defect (last updated June 23, 2024) (emphasis in original).

In the context of product liability, the definition may assume a more precise legal meaning. A common legal reference defines "defect" as "[a]n imperfection or shortcoming, esp. in a part that is essential to the operation or safety of a product." Black's Law Dictionary (11th ed. 2019). Black's Law Dictionary further defines a "design defect" as "[a]n imperfection occurring when the seller or distributor could have reduced or avoided a foreseeable risk of harm by adopting a reasonable alternative design, and when, as a result of not using the alternative, the product or property is not reasonably safe." *Id.*

The Commission has the burden of proving that the Podsters are "defective," as that term is defined. Its proof problems on that question begin here, at the root. Neither the CPSC's own fundamental definition of the term, nor a basic, common understanding of "defect," nor the legal dictionary definitions are satisfied by the evidence adduced at trial.

The Commission has essentially asserted that the "fault, flaw, or irregularity" that "impairs [the] quality, function, or utility" of the Podsters is that they are not a flat, firm surface, inclined no more than 10 degrees and approved by the CPSC for infant sleep. In suggesting this as a basis for deeming the product "defective," the CPSC introduced no evidence of any comparable product outside of the narrow class of infant sleep products approved by the CPSC which would *not* be defective.

No competing product within the class of infant loungers or pillows was provided as a direct comparator for the Podsters. No product was introduced as an example of a lounger or pillow that did not bear the same "weakness" or "shortcoming" as the Podster. No "reasonable alternative design" was discussed or suggested to remediate the "imperfection" in a way that

"could have reduced or avoided a foreseeable risk of harm," except for the aforementioned sleep surfaces approved by the CPSC for infant sleep.

Mannen's conclusion about the Podsters is unpersuasive because it entirely fails to account for an important distinction between the Podsters and the inclined sleep products she tested and relied on in reaching her conclusion: the inclined sleep products were intended for sleep. *See* CCX-1, at 33 ("One can conclude that the Leachco Podster is dangerous in manners similar to how those inclined sleep products were found to be dangerous.") But the Commission has acknowledged from the beginning—in the Complaint—that the Podster is not marketed for use as and has never been advertised as a sleep product. Compl., ¶¶ 13-14.

The Commission attempts to sidestep this problem by citing to foreseeable misuse. But its own expert appears not to have been troubled by, or even to have considered, important factual distinctions between a product intended for sleep and one intended for use as an intermittent seat during waking hours.

First, the time element involved is completely different. It is commonly known, by anyone with any experience as a parent or caregiver, that babies spend much of their time sleeping. As research cited by Katwa and Kish noted, infants spend most of their time sleeping. A fair portion of that sleep occurs at night when an infant may be expected to sleep for several hours, although Katwa testified that a regular pattern of sleeping through the night typically does not emerge until six months of age.

This is distinguishable from the intended use of the Podster. Arguments about the degree and danger of misuse of the product does not change the fact that Mannen has compared body positioning in two different types of products, with two distinguishable use profiles, as though the difference in those profiles does not matter. Yet in a product designed and marketed for sleep, the infant would more likely be intentionally placed in the product for a longer period, consistent with its intended use.[27]

Similarly, sleeping infants are not usually continuously supervised by an adult. This factor compounds the use of unsafe sleep products. But again, the Podster is in a different class of product, and consumers are advised not to leave an infant unsupervised in the Podster.

While it is possible that caregivers may leave infants unattended in the Podster, it is more likely expected that they would do so, and for longer periods of time, with a product intended, designed, and promoted for use as a sleep environment. Complaint Counsel, relying on Kish,

[27] When Mannen did consider time in relation to the Podster, it undercut her conclusion. She held that it would be easier for an infant to roll into a prone position on the Podster than on a flat surface, and that if that happens, "there is an increased risk that oxygen will dip below dangerous thresholds *in a very short amount of time* due to the soft and plush surface which envelops an infant's face." CCX-1, 43 (emphasis added). The product's use history and the number of injuries related in any way to the product is inconsistent with the suggestion that the product creates conditions that may easily put an infant in a compromised position, where dangerous oxygen deprivation would quickly result.

argues that the Podster requires constant adult supervision, unlike its approved sleep products. *See* Complaint Counsel's Post-Hr'g Br. (hereinafter "C.C. Post-Hr'g Br.") at 10, 11, 26 (citing CCX-2, at 66-67). This difference in the intended use is not addressed.

Kish's testimony may bolster the argument concerning the feasibility and dangers of misuse, but Mannen's testimony relies heavily on comparisons to other products which seem to have a greater number of serious injuries arising from their use.[28] Thus, she effectively compares the Podster to an ideal safe sleep environment—even though the product at issue is not marketed or intended as a sleep product, and even though it warns consumers not to use the Podsters for sleep—and finds it lacking because it shares attributes with sleep products the CPSC has deemed dangerous. However, she never addresses the distinguishing fact that those products were designed, intended, and marketed for use by sleeping infants.

The core of the CPSC's challenge to the Podster's design, then, is that it is part of a class of products that are categorically defective. Its supposed flaw is that it includes features—such as padded sides and a design that places the infant in an inclined, seated position—that may be commonly found in infant sleep products, loungers, and pillows, as well as other infant products not designed or intended for sleep, such as swings and car seats.

The reliance of Complaint Counsel's own expert witnesses upon studies that examined a spectrum of products which bore the same "defects" as the Podster—i.e., products that positioned infants in what they considered to be an excessively inclined position and/or surrounded infants with padding that they said presented a suffocation hazard—is telling. The record speaks of common hazards created by these features, yet among products not intended for sleep, the Podster has been singled out as uniquely, or at least distinctively, "defective."

The reason for this is never explained. The prevalence of similar features in a variety of products would seem to make it difficult, if not impossible, to condemn these common characteristics as "defects" because they are, apparently, normal and not "abnormalities." They do not "impair" the function of the products so designed, but must serve the products' function in some way, because so many products share the same attributes. The features are thus regular and not "irregularities."

For example, Mannen repeatedly faulted the Podster for its differences in positioning when compared to a firm, flat crib mattress. But studies she relied on noted that it was effectively impossible to position infants at a 30-degree incline on a flat mattress, because they would slide down the incline. CCX-1, at 39. Thus, the study concluded that inclined sleep products require a seat design feature to prevent infants from sliding at higher inclines," placing them in a "position that might more accurately be considered a reclined sitting posture than a lying posture." *Id.*, *citing* Wang 2020, *supra*. *See also* CCX-1, Ex. B, at 63 (comparing incline

[28] It is important to distinguish between the number of injuries in a given period and the *frequency* of injury from use of a product. It would not be possible to draw any conclusions about frequency without more extensive sales and consumer usage data about the products being compared, and even then, the number of variables affecting the analysis would be daunting. But this is an evidentiary weakness that Complaint Counsel failed to anticipate or remedy in constructing a case based on comparisons of diverse product types with similar features.

angles, stating that 30% incline cannot be considered a lying posture, and criticizing inclines greater than 10%).

Mannen never discusses the potential advantages of a "reclined sitting posture," despite its prevalence across a range of different product types, including the Podster. But there must be a reason why caregivers would want infants in their charge to be so positioned, and there is certainly a distinction between products designed for sleep, to which Mannen has generally compared the Podster, and those designed for other purposes. Such distinctions are never addressed by Complaint Counsel, even though Mannen said that she had studied other products and noted their positive attributes in the past. *See* Tr. Vol. I, at 164-65 (discussing study of infant carriers).

Complaint Counsel's case abandons redemption of the product by improved warnings (Kish) or better, safer design (Mannen, Katwa, and Kish). The witnesses seem to agree with each other that there is no such thing as a safe infant lounger, and that because only a CPSC-approved sleep surface is appropriate for sleep, a product which may be used episodically, inadvertently, or routinely for sleep in contravention of its warnings and instructions must be removed from the marketplace.

But this is not a proceeding aimed at banishing all infant loungers or all products of any given type. This proceeding has singled out one company and its products for legal action. If there is a defect in the product's design, the CPSC must bring that defect in relief, by comparison to similar products which are not defective, because a defect must be the factor that creates the risk of injury.

The absence of evidence of a safer alternative design or a safer product within the class of infant loungers, alone, may therefore be sufficient to refute the existence of a design defect in the Podsters, based on the common understanding of the terms "defect" and "design defect." *See* Restatement (Third) of Torts: Product Liability, §2(b) (Am. Law Inst. 1998) (design defect exists where foreseeable risks of harm could have been avoided or diminished by adoption of reasonable alternative design, the omission of which renders the product not reasonably safe). Complaint Counsel's own witnesses believe that there is no way to improve the product, and no way to effectively warn against its supposed dangers, which are hardly manifest or obvious, and which required three experts together to gather a theory of prospective harm threatened by the misuse of the product.

Nevertheless, the regulation uses the traditional definition of the term "defect" as a starting point and expresses factors that the Commission may consider in determining whether a product defect exists. The Commission is not bound by or limited to a dictionary definition or common understanding, because the CPSA and its regulations have made clear that the Commission defines "defect" more broadly, considering factors extrinsic to the product design. *See Zen Magnets, LLC v. U.S. CPSC*, No. 17–cv–02645–RBJ, 2018 WL 2938326 at *5 (D. Colo. 2018), *aff'g In the Matter of Zen Magnets*, No. 12-2, 2017 WL 11672449 (CPSC, Oct. 26, 2017) (hereinafter "*Zen Magnets Initial Decision*"), *rev'd in part on other grounds sub nom Zen Magnets, LLC v. CPSC*, 968 F.3d 1156 (10th Cir. 2020) (CPSC has broad latitude in construing

"defect" under section 15(b) of the CPSA and interprets it "to include the broadest meaning found in Federal and State Statutes and judicial pronouncements.")

The factors the Commission has thus identified as relevant to its determination, including foreseeable product misuse, therefore must be weighed to see if they may support a finding that the Podsters have a design defect, despite the absence of evidence of features or characteristics that may be isolated as distinctively and aberrantly dangerous in the use of the product.

i. The Podster Is a Useful Product, But Not a Necessary One

Complaint Counsel asserts: "The Podsters do not offer utility for consumers." C.C. Post-Hr'g Br., at 23. This is disproved by economic data and common sense. Respondent has distributed approximately 180,000 Podster products in commerce since 2009. The parties have stipulated that the products were sold at a retail price of $49-$89.

It is inconceivable that scores of thousands of consumers would pay nearly $50 and as much as $90 for a product offering no utility. One can only reasonably conclude that Respondent's conception and marketing of the Podsters was successful in identifying a consumer need and fulfilling it to a certain extent.

While the Podsters may therefore be described as a useful aid for busy caregivers, the evidence does not support a finding that it is an essential one. If the Podsters did not exist, the CPSC has argued that other Commission-approved products could fulfill the same role, including playpens and play yards, bassinets, and cribs meeting the CPSC's safety standards. *See* C.C. C.C. Post-Hr'g Br., at 26, *citing* Tr. Vol. IV, at 27-28 (On cross examination, Shibata acknowledged that safe alternatives were available).

This may be plausible, but it is not certain. Deprived of a choice between the Podster and a CPSC-approved sleep device, consumers might exclusively use the latter. Or, as Shibata suggested, and as a PSA conducted for the Podsters acknowledged, consumers might choose another of the numerous substandard options available to them. This might be more likely if the CPSC-approved options were not as useful, convenient, portable, or comfortable as the Podster, or other, less-safe options. And as the Commission argues, persons of limited means may have fewer options available. See Compl., ⁋ 20.

But while the Podsters are apparently useful, it cannot be said that they are "necessary." Nor can it be said that the alleged danger posed by the product is integral to its function in the same way that the sharpness of a knife—which may present a deadly hazard if used improperly—is essential to its very purpose.

Perhaps of greater direct relevance is the fact that the Podster is not necessary in the way infant car seats—which are required for use by law in every U.S. jurisdiction[29]—are necessary. Thus, the necessity for car seats may justify risks and trade-offs greater than those warranted for

[29] *See* Child Passenger Safety, Governors Highway Safety Association, https://www.ghsa.org/state-laws/issues/child%20passenger%20safety (last updated Apr. 2024) (chart showing requirement in all U.S. states and territories to provide child restraints).

a product where its use is not compelled by law. *See ASG Indus., Inc. v. CPSC,* 593 F.2d 1323, 1334 (D.C. Cir. 1979), *citing* 15 U.S.C. § 2058(c)(1)(C) (hazards that may bar one product from the marketplace "may be compatible with continued production and sale of a product for which there is a substantial public need").

But even if the Podster is not "necessary," it has some demonstrated utility, and the challenged characteristics of the Podsters do appear to serve its utility and function. The fact that many other infant products not intended for sleep place the occupant in an inclined position greater than 10 degrees strongly suggests that the incline is purposeful and functionally useful.

One can imagine why this is, even though scant evidence was introduced at hearing concerning the benefits of an angled, inclined posture. A newborn or very young infant cannot sit fully upright because a child at that age cannot hold its head up. *See* CCX-1, at 24 (noting limited ability of infants to control their heads and necks). Sitting at an incline permits the child to better see and interact with surroundings and other persons than a completely supine position.

There is no need for such interaction when the infant is sleeping, of course. But the fact that a diverse array of products, including car seats, swings, and rockers, feature similarly angled seating positions suggests the utility of the position serves, rather than impedes, the product's usefulness.

Somewhat ironically, Kish's recitation from *New York Magazine's* product review blog may provide the best illustrative support for the Podster's form serving its function:

> Holding and feeding your baby all the time is exhausting. The little nugget spits up post-feeding and you don't want to lay them flat all the time because "flat head syndrome" is a real thing. Hence this pod. The sides are contoured so the baby is snug, secure, and also slightly elevated. . . . *No other seat out there "snuggles" the baby like this one.*"

CCX-2, at 42-43, *citing* Krinsky *supra* (emphasis in Kish testimony).

While Kish's excerpt goes on to include the author's praise of a product that "**essentially lulls the baby to sleep without any bells and whistles,"** and the attribution of her discovery of the Podster to "secret mom knowledge," the excerpt does show that the product's design serves its function in a way that caregivers may find useful. CCX-2, at 42-43 (emphasis in Kish testimony).

Kish herself claims that *New York Magazine* is a publication that most consumers would likely view as a credible, neutral reviewer of consumer products." CCX-2 at 43. While she is alarmed about the implications of this, *see* Slip Op. at 20, *supra*, the Commission's assertions about a lack of utility reflect a failure to consider both the pros and cons of the product's design.

As suggested by the product review in *New York Magazine*, the padding that surrounds the infant in the Podsters provided as exhibits helps to contain and "snuggle" the infant within the product. One of the very dangers the Commission cites is the risk of the infant moving off the product. But the possibility that the product's padding might help keep an infant in a stable

position during the brief intervals when it is intended to be used is never considered. *See* RX-1, at 21 (Shibata criticizing the CPSC for failing to address the role the Podster's padding might play in preventing an infant from rolling from supine to prone position).

This failure to consider the Podster's form and function in service of its utility resulted in a product safety case where no Commission witness suggested an alternative, safer design, except to state that the products should effectively conform to the form and material used in flat crib mattresses. *See, e.g.*, CCX-1, Ex. B, at 64 (recommending that sleep product materials and shape be flat and meet standard for crib mattresses).

Similarly, the Complaint faults the lack of a rigid frame structure in the abstract, but Complaint Counsel did not present any evidence showing that an alternative design featuring such framework would have been safer. In fact, some of the products reviewed by Mannen in her 2019 study of infant sleep products included rigid frames, but this was not cited as a feature that made those products less hazardous. *See* CCX-1, Ex. B, at 10-14, Table 1.

In sum, the Podster is a niche product, designed to fill a limited supportive role for caregivers who need a place to rest an infant for short intervals during the day. Some consumers found this to be helpful enough as a concept that they were willing to buy the product. Some reviewers extolled its benefits. *See* Slip Op. at 20-21, *supra*, *citing* CCX2, at 42 and CCX-2, Ex. 8 (reviews by *New York Magazine* and *The Stork List*). While Kish viewed those reviews with some alarm, based on their endorsement of product misuse, the features cited could also serve the proper use of the product.

The Commission utterly fails to address this utility of the product for its intended use, except to disparage it in comparison with approved sleep mattresses or by association with sleep products—a category with a different intended use—which it has characterized as dangerous, and which have now been banned. Yet as Shibata noted, "a balance of utility and associated potential risks must be considered." RX-1, at 10.

ii. If the Podsters Were Dangerously Defective, the Persons Exposed to the Risk of Injury—Infants—Would be Vulnerable and Totally Dependent on Adult Care and Supervision, but Complaint Counsel's Witnesses Have Not Considered Misuse and its Consequences in Context.

As an infant product, the Podsters—if defective—would expose a highly vulnerable class of persons to a risk of injury or death. Infants are almost entirely dependent on adult caregivers for their every need. An infant has no agency in choosing where to be placed, for how long, or in what surrounding circumstances. And young infants generally lack the strength, experience, or physical capability to extricate themselves from a precarious or dangerous situation without adult assistance.

The CPSC has produced sufficient evidence to support a theoretical possibility that an infant left unattended or permitted to sleep in a Podster *could* suffocate and die. Thus, there is at least the potential for a fatal injury to result from misuse of the Podster. This misuse is foreseeable because, as Katwa testified, infants sleep throughout the day, and as Kish explained,

caregivers could be tempted to permit an infant to continue sleeping unsupervised or could decide to use the Podster as a sleep product, despite the product warnings.

In particular, Katwa's testimony about infant physiology and breathing showed why infants may be especially vulnerable to sleep and breathing disorders. While Shibata's testimony was helpful in identifying weaknesses, omissions, and reasonable questions about Mannen's methods, techniques, and assumptions, she was not qualified to critique Katwa's medical opinion and did not do so.

As Katwa explained, infants have smaller, more delicate air passages, are generally obligate nasal-breathers who may not be able to breathe sufficient air through their mouths if their nasal passages are blocked, and have different chest shape and physiology than adults. Additionally, he noted their much greater oxygen and metabolic demands, relative to their size.

Infants within the age range targeted for use of the Podsters therefore are clearly vulnerable. Without constant adult support, they are in fact helpless. However, Complaint Counsel's case against the Podster fails to consider the role of caregivers, their responsibility, and whether they generally safeguard infants against the risks of injury from misuse of the product.

While Kish posits that consumers in effect cannot be trusted to use the product safely and as directed, based on comments posted in public fora, and while she did show that it is possible for misleading information on use of the product to be published, she acknowledged that she can't quantify the general response to these comments. And while Kish testified that multitasking with an infant cannot be safely and effectively done, Shibata's characterization of "constant adult supervision" as requiring an adult to be present and attentive in the same room is not unreasonable.

Neither Kish nor any other witness can reliably attest to the habitual care provided to infants by caregivers who choose to use a Podster to help them balance their responsibilities. What can be—and has been—quantified is the number of injuries resulting from misuse of the product. That number is, at most, three in more than 12 years.

Even that number is questionable. There is conflicting information in the IDIs conducted into the deaths. Only one such death involved the parents of the deceased child, and that death resulted from bed sharing—itself deemed an unsafe practice by Complaint Counsel's witnesses.

The Commission does not need to prove that the Podster actually caused any of the three deaths to which Complaint Counsel has related its use. But the context of infant deaths, including sleep-related deaths, needs to be accounted for and has not been.

Somewhere between 1,000 and 3,500 infants die unexpectedly in their sleep every year.[30] Complaint Counsel's own witnesses have relied upon and produced evidence showing that other

[30] It is not necessary to fully extrapolate the number of infants at risk, but even the large (continued . . .)

products have played a role, according to the scientists who reviewed the incidents, in the deaths of a significantly greater number of infants. And Mannen's work shows a consistent involvement of more than one unsafe sleep factor in every death cited in her study of pillows.

We know that consumer misuse must play a role in any product hazard determination for the Podster, because there has never been an injury reported where the product was used as intended. We do not have a means of apportioning responsibility between any alleged design defect and consumer misuse, because the reports that exist, and the investigations into the incidents, are inconclusive. But the available evidence strongly suggests that caregiver misuse was the dominant factor. In all three incidents, the product was used intentionally as part of a sleep environment, which is contrary to the manufacturer's intended use of the Podster and warning labels for the product.

The evidence in context thus suggests that most parents do not routinely place their children in a Podster, unsupervised, for sleep. As noted above, the only incident involving parents was a co-sleeping death. As Kish noted, co-sleeping is not safe and has been growing in popularity. Complaint Counsel's case did not deal with this fact, or its implications. But while the incidence of SUID has declined dramatically in the past three decades, the number of deaths, in an absolute, human terms, remains high.

It is natural to want to reduce that death toll by any means necessary. But if the Podsters were a substantial part of the problem, and misuse were as prevalent as Kish believes it to be, the vulnerable infants imperiled by misuse would "easily" find themselves in a compromised position, as Mannen testified. And, as a consequence, the physiologic effect would be compromised breathing and serious injury or death, as Katwa testified.

That confluence has not materialized. If the Podster were the common, injury-producing factor imperiling infants, the data would support the posited conclusion about the Podster's inherent danger.

There are only three logical reasons why the real-world experience would not conform to Complaint Counsel's theory. Perhaps the Podsters are not as dangerous as Complaint Counsel asserts. Maybe caregivers are more attentive to warnings and watchful over the infants charged to their care than Kish believes them to be. Or the real-world performance of the Podsters might be the result of sheer good fortune.

Either of the first two possibilities would be fatal to Complaint Counsel's case, and the third is purely speculative and impossible to prove. But what has been proved is that infants are only at risk if safe sleep procedures are disregarded, and that there are numerous other

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[30] (. . . continued)
number of annual infant sleep deaths may not fully express necessary context. According to the Centers for Disease Control and Prevention, nearly 3.7 million children were born in the Unites States in 2021. Brady E. Hamilton, et al, Births: Provisional Data for 2021, National Vital Statistics System Rapid Release Report No. 20 (May 2022). The birth rate in the United States has been declining steadily since the 1990s. *Id.* Nevertheless, it is reasonable to expect several million live births per year, based on the government's published data.

circumstances not involving the Podsters—a product targeted by this action as an especial hazard—which seem to reflect a more substantial threat to public safety. The evidence of record does not establish a pattern of defect that creates a danger to the vulnerable population, even if product misuse is accepted as a possibility.

iii. The Podsters Do Not Present an Obvious Danger, and While its Warnings Could be Better Designed, They Appropriately Advise Against Misuse—Which is Nonetheless Foreseeable, to a Certain Extent.

The "obviousness" of the possible risk of injury from use of the Podster must be considered in connection with the purpose of Section 1115.4. The regulation focuses on the duty of manufacturers and others in the product distribution chain to inform the Commission when they receive information that a product contains a defect which could create a substantial product hazard. 16 C.F.R. § 1115.4.

An express limitation in the regulation provides that, "[d]efect, as discussed in this section and as used by the Commission and staff, pertains only to interpreting and enforcing the Consumer Product Safety Act. The criteria and discussion in this section are not intended to apply to any other area of the law." *Id.*

This does not constrain the use of the definition and analytical guidance in the regulation to the duty to report, but "obviousness" as a factor clearly relates to the duty to recognize and provide notice of defects not only when they become manifest through an injury, but when a reasonable person would have recognized the risk and alerted the public to it or taken other action required by the CPSA.

Complaint Counsel has acknowledged that it knows of only three incidents where a Podster may have been used in a setting where an infant died. There are no other reports of a Podster ever being implicated in the injury of any person.

Also conceded is that the Podster was not used in a manner consistent with Respondent's warnings and instructions in any of the three fatal incidents. Thus, there is no evidence of any person ever being injured when a Podster was used as intended and as the product's instructions and warnings direct. This includes a total lack of evidence that any infant has ever fallen from an elevated surface upon which a Podster has been placed.

There is no apparent or obvious danger to the Podster. In fact, Complaint Counsel's theory is that the hazard presented by the product is not obvious but concealed. C.C. Post-Hr'g Br., at 27. Kish's assertions that the product's innocuous nature and its similarity to a common pillow may give caregivers a false sense of security defuse any argument that could be made about the Podster presenting an obvious risk of injury.

The appropriate remedy is to place consumers on guard against the hidden danger. But it is undisputed that Respondent anticipated the potential non-obvious hazards arising from certain uses of its products and has provided appropriate warnings and instructions. This is clear from

the CPSC's own allegations in the Complaint, which detailed the warnings Respondent provided against the very uses the CPSC has cited as creating a risk of injury.

While the warnings targeted the appropriate hazards from misuse, their adequacy was questioned. Kish's testimony about warnings, and the sources she cites, seem credible in their explanations of the effectiveness of color, contrast, placement, consistency, etc. But there is no evidence that improvements in the warnings would mitigate any potential danger. On the contrary, Kish herself testified that there is *no* warning that would reduce the risks and hazards arising from misuse of the product.

Because Complaint Counsel must effectively concede that additional or improved warnings would have been useless, based on his own expert's opinion on the matter, the absence of warnings is also a non-factor in the defect analysis.

This may not wholly resolve the question of a product defect. The CPSC's regulations include consumer misuse, and the foreseeability of that misuse, as factors to be weighed in a product defect analysis. This potential for misuse is the only remaining basis on which a product defect could be predicated and was the focal point of expert testimony by Complaint Counsel's witnesses.

Kish's expert opinion and testimony provided evidence that some consumers misuse the Podsters for infant sleep. We know that it is foreseeable that this will happen, because there is evidence of three incidents of injury involving misuse of the Podsters in the record, as well as documentary evidence of other consumers using the product for sleep.

The ample evidence showing that use of the Podsters for sleep is not uncommon includes testimony from Tonya Barrett, Respondent's compliance coordinator, and Jamie Leach, who was aware that her own daughter had allowed Leach's granddaughter to sleep on the product. And at least some messages from parents and other consumers, as well as public websites providing product reviews, encouraged the use of the Podsters for sleep, contrary to the product's instructions and warnings.

The question is whether that propensity for misuse is sufficient to support the allegation of a defective product design. To establish that, Complaint Counsel must at least prove that the design of the product contributes to misuse, so that there is a demonstrated link between misuse and design sufficient to establish a "substantial risk of injury to the public," or an unreasonable risk of injury, created by the design.

As noted in the previous section's discussion of the vulnerability of infants and dependence on adult care, misuse of the Podster is either not as widespread or not as dangerous as Complaint Counsel's witnesses believe it to be. Counsel argues that the design of the Podster does facilitate co-sleeping and that its simplicity lulls consumers into misusing it for sleep.

But evidence about the feared consequences arising from that misuse do not show that the product has a "defect" that leads to dangerous misuse. Shibata overreached in arguing that the Podster's design must be shown to be "uniquely" dangerous. But it must at least be distinctive,

in the sense that there must be evidence that there is something "wrong" with the product *design* that substantially contributes to the supposed danger, in a way that a different product would not.

This is best illustrated by the Texas co-sleeping case, where the photographs taken at the scene and included in the IDI show at least three other infant sleep or lounger products in the home. If the Podster had not been available, would the parents have forsaken co-sleeping? Or would they have simply chosen from among the other products available to them in their own home?

This question is a paradigm of the behavior and modification problem confronting the CPSC as it seeks to reduce infant sleep deaths. There is not a single piece of evidence that shows that the Podsters have been broadly misused because the design of the product lured caregivers en masse into placing the children in their care in a dangerous setting.

Complaint Counsel does argue that Respondent should have done more to dissuade misuse of the product. Respondent counters that it scrupulously reminded consumers who contacted it directly not to misuse the product. There is no evidence of any instance where Respondent's corporate leadership communicated a tolerance for misuse.[31]

Complaint Counsel need not prove that the Podster is the proximate cause of any injury. But they must prove that the danger is real, and not illusory; that it is present, and not speculative or remote.

The evidence is not up to that task. It does show the vulnerability of infants to injury, and that injuries may occur under certain conditions, but is unpersuasive in its attempts to show that the Podster's design is an appropriate focal point for corrective action to protect infants from harm.

[31] At hearing, Complaint Counsel introduced a photograph it had discovered during a contemporaneous search for images of the Podster being used for sleep, showing that a comment from Respondent's own official Instagram account had liked the image. Tr. Vol. II, at 99-102; CCX-59. The photograph was admitted over Respondent's objection. Complaint Counsel sought to introduce the photograph in apparent response to Respondent's cross-examination of Kish, in which it suggested that Respondent had always discouraged misuse of the Podsters for sleep. There are two problems with Complaint Counsel's argument. First, the photograph which was "liked" is almost objectively adorable. Thus, a natural, unguarded human reaction "liking" the photo may be understandable. More importantly, there is no evidence as to who liked the post, or that Leachco's management was aware of it. The evidence is thus not especially probative, is not corroborated by other proof, and seems at odds with Complaint Counsel's own evidence about Tonya Barrett's firm stance against use of the Podster for sleep within her own family.

2. Product Liability Law has Some Commonality but Does Not Directly Address the CPSC's Mission, and the CPSC's Own Precedents that Do So Do Not Support Complaint Counsel's Theory.

i. Product Liability Law Has Not Been Pre-empted, but its Ability to Protect Consumers is Complementary to the CPSC's Role.

Product liability suits at common law are intended to provide compensation for injuries caused by defective products. The CPSA, on the other hand, is intended to prevent defective products from harming consumers, by requiring warnings, instituting recalls, or by banning a product or class of products.

A legal distinction has been noted between actions that are compensatory, and those that are regulatory, and a suit may be pre-empted if it imposes a regulatory requirement inconsistent with federal law. *See Mut. Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 480, 487 (2013) (disapproving of party's argument that drug labeling requirement implicit in state cause of action was purely compensatory and holding that it conflicted directly with federal law prohibiting generic drug makers from changing product labels).

The CPSC has not pre-empted the field of product safety regulation here. No pre-emption claim has been made, and the number of product liability lawsuits filed in this country likely numbers in the thousands every year. The aim of those lawsuits is, principally, compensatory, and is distinguishable from the CPSC's general regulatory role. *See Southland Mower Co. v. CPSC,* 619 F.2d 499, 513 (5th Cir. 1980), *citing U.S. v. Gen. Motors Corp.*, 518 F.2d 420, 433-34 (D.C. Cir. 1975) (determinations of fault or liability relevant to award of damages not determinative to meaning of "defect" in prophylactic provision of federal highway safety statute).

However, the determination of "unreasonable risk of injury" may involve "a balancing test like that familiar in tort law: The regulation may issue if the severity of the injury that may result from the product, factored by the likelihood of the injury, offsets the harm the regulation imposes upon manufacturers and consumers." *Id.* at 508-09, *quoting Forester v. CPSC,* 559 F.2d 774, 789 (D.C. Cir. 1977) (relying on the definition of "unreasonable risk" in Federal Hazardous Substances Control Act, 15 U.S.C. § 1261(s)).

There is some congruence between the legal concepts applicable to product liability suits. Under Oklahoma law, for example, "[a] product's design renders it defective when the product is not 'safe for normal handling and consumption' in accordance with the expectations of the ordinary consumer." *Youngberg v. Gen. Motors,* No. 22-7047, 2023 WL 7126422, at *3 (10th Cir. Oct. 30, 2023), *citing Duane v. Okla. Gas & Elec. Co.*, 833 P.2d 284, 286 (Okla. 1992). An "unreasonably dangerous" product is one that is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." *Youngberg,* 2023 WL 7126422, at *4, *citing Kirkland v. Gen. Motors Corp.,* 521 P.2d 1353, 1362-63 (Okla. 1974).

However, while both legal actions include a consideration of unreasonable risk of injury, the Commission is not bound by the requirement to establish the same elements as a plaintiff in a private cause of action. Product liability precedents, which include a requirement to show damages proximately caused by the product defect, are therefore not directly relevant to the decision of a product defect under the CPSA.

ii. The CPSC's Precedents are Distinguishable and Do Not Support the Complaint Against Respondent.

Complaint counsel has cited to CPSC and court precedents. But the cases are distinguishable because they show how product design defects caused, or could be a direct and substantial factor in causing, injury to members of the public. While product misuse was a factor in those cases, their focal point was the design of the products at issue, including especially aspects or features of the project that created the danger.

Complaint Counsel's reliance on *Zen Magnets Initial Decision* is unpersuasive because the evidence there established a clear link between the product's distinctive characteristics and the potential for injury.

In that case, the small rare-earth magnet sets were more powerful than magnets permitted in toys *because of* the potential for injury strong magnets would pose if swallowed by children. *Zen Magnets Initial Decision*, 2017 WL 11672449, at *2.

The CPSC found that the magnets were intended to be separated and reattached; they were marketed in part to adults using a video urging consumers to "Never Let Go of Childhood Wonder," and for use in arranging jewelry or refrigerator art. *Id.* The Commission's expert concluded that, "[t]he very design of the Subject Products as small, loose, separable, high flux [a measurement of magnetic power] magnets is hazardous to children." *Id.* Witnesses further noted that the "'shiny, reflective, and smooth'" magnets "look like candies that are sometimes found on cakes and cookies." *Id.*

Young children might put the magnets in their mouths intentionally or accidentally, while "tweens" and teenagers (children aged nine to 16) might use the magnets to mimic facial piercings, place them on their braces, or put them in or near their mouths while playing with them and swallow the magnets accidentally. *Zen Magnets Initial Decision*, 2017 WL 11672449 at *2-3. This behavior is considered normal and age appropriate for both groups of children. *Id.*

The consequences of accidental ingestion could be both devastating and difficult to diagnose and treat. If more than one magnet were ingested, or if one of the magnets and a metallic object were both ingested, the magnets could attract to each other or to the metallic object across bowel or other tissue. *Id.* at *3. Once so affixed, the magnets could not be separated, and the pressure *caused by the magnets* could cut off the blood supply to tissue or cause fistulas or perforations. *Id.* The result could be tissue necrosis, serious infection, sepsis, and death. *Id.* Further, the symptoms caused by ingestion of the magnets could mimic other ailments, and even if they were identified as an ingested foreign object, doctors might not be

aware of the special danger posed by the magnets. *Id.* The resulting delay in diagnosis could result in serious injury. *Id.*

Complaint Counsel reads too much into the Commission's reversal of the ALJ's initial decision. Complaint Counsel correctly quotes the Commission's holding, in *Zen Magnets Initial Decision*, that an action may be pursued under section 15 of the CPSA "based *solely* on reasonably foreseeable misuse." C.C. Post-Hr'g Br., at 23, *quoting Zen Magnets Initial Decision*, 2017 WL 11672449, at *9 (emphasis added in brief).

But the context is crucial. The Commission's extensive critique of the judge's conclusion is grounded on the erroneous conclusion that foreseeable misuse use alone was insufficient to support a defect charge under section 15(2), and that a product may not be found to be defective if no injuries would be produced if the product were used as intended. *See Zen Magnets Initial Decision*, 2017 WL 11672449, at *9-13 (citing extensively to text of regulations, precedent, and legislative history to refute "proposition that only the proper or intended use of a product can give rise to a defect determination.")

"Solely," as held by the Commission, does not mean that the product's characteristics are irrelevant to the consideration, such that misuse which produces or causes injury could have produced the injury whether or not the product was involved. The Commission thoroughly analyzed the product characteristics in *Zen Magnets Initial Decision*, noting both their attractiveness to misuse by children engaging in age-appropriate behavior (supporting foreseeability) and the devastating consequences of such misuse *caused by* the size and strength of the magnets in question.

Unlike the present case, where Complaint Counsel has failed to link persuasively the product characteristics to the risk or cause of serious injury in similar products with the same characteristics, the Commission in *Zen Magnets Initial Decision* noted that serious injuries had been produced because of the same characteristics in other products (other high-powered, small rare-earth magnet sets) *created* the risk of serious injury. *See Zen Magnets Initial Decision,* 2017 WL 11672449, at *13-14 (conclusion that characteristics create the risk of injury supported by reference to other cases involving magnets with similar characteristics.)

Here, the only common element connecting the Podsters to other products involved in infant sleep deaths is the misuse. Mannen studied a variety of products with different purposes and different features. The commonality among the infant deaths where these products may have been involved was a compound, hazardous sleep environment involving at least two hazardous factors.

In the Matter of Dye & Dye, 1989 WL 435534 (CPSC, July 17, 1991) is similarly distinguishable. The product there was a high-voltage worm probe (a product used to generate an electrical current to drive earthworms to the surface, so that they may be collected) that "violated basic principles of electrical design" by employing exposed (uninsulated) parts that conducted electrical current to the ground. *Dye & Dye*, 1989 WL 435534, at *1, *5. The product was intended to be used in moist soil and created a risk of fatal electric shock by contact with either the exposed probe or the electrified ground. *Id.* at *5.

There, as in *Zen Magnets Initial Decision*, the Commission focused on the particular characteristics giving rise to the danger. Complaint Counsel focuses on the Commission's holding that it need not show that a product was the cause in fact of any injuries or deaths to find a defect. C.C. Post-Hr'g Br., at 34-35. But while the manufacturer argued that no fatalities had been caused by its products, the Commission noted that 28 deaths had resulted from the use of substantially similar products with the same characteristics. *Dye & Dye,* 1989 WL 435534 at *6.

There, too, the focus was on the distinctively dangerous characteristics of the products. And unlike this case, the Commission engaged in an extensive and thoughtful examination of the risk against utility of the product. *Id.* at *9-11. This included the ALJ noting that the manufacturer had not addressed the question of whether worms could be driven to the surface by a lesser, non-lethal voltage than the 120 volts carried by the product. *Id.* at *9.

In *Southland Mower Company*, the court likewise focused on the potential harm from a design flaw—the ability of consumers to defeat a safety guard—in addition to consumers' propensity to do so, if the guard interfered with performance. 701 F.2d at 513-14. Thus, the Commission correctly related a characteristic of the product's design to the potential for misuse.

In sum, a review of Commission precedents only serves to highlight the Commission's appropriate focus on the dangerous characteristics of products, and how those characteristics could produce severe injury or death. While foreseeable misuse is an appropriate consideration, misuse that could produce the same result without the product's involvement, alone, is insufficient to show that the product *creates* the risk of injury.

iii. The Commission's Experience in Product Safety Entitles it to Some Deference on Product Safety and the Need to Protect the Public, but it Must Connect the Remedy it Seeks to the Alleged Risk of Harm and Must Consider Utility in its Actions.

The CPSC's experience and the opinions of its staff appear to have been hugely influential in the decision to target the Podster. There can be no doubt about the sincerity of the commitment to infant safety exhibited by the CPSC's staff or Complaint Counsel's witnesses. Mannen and Kish, in particular, are personally and deeply invested in the Commission's regulation of infant sleep products.

However, the agency's experts adhered to a generally consistent opinion that the Podster is dangerous, not because of any distinctive features or characteristics, but because it is not a flat, generally level, firm surface with some means of preventing the infant from leaving the device without a risk of being entrapped by those means, i.e., a CPSC-approved sleep product.

The Podster appears to have been targeted as an exemplar for a class of products with common features. Designed for infants to rest in an inclined, supine position, the product uses sides made from formed, padded foam that is semi-rigid to support and contain the infant on the product. Mannen has studied numerous products, some with similar characteristics. But all of

the products have been compared to an ideal sleep environment and found wanting for failing to meet the characteristics of that environment.

This generalized approach deprives the case of the requisite focus on product features. While Complaint Counsel asserts that the Podsters share common characteristics with another product, the Boppy infant pillow, which was recalled in September 2021, C.C. Post-Hr'g Br., at 30, no evidence was produced at the hearing to show such commonality. Mannen did not directly compare the Poster to the Boppy or to any other product in her testimony to show that the Podster harbored a similar defect, or that the same features present in both products were responsible for any infant deaths. And the circumstances of the recall were not introduced into evidence.

Complaint Counsel tries to avoid the need for such comparisons by taking the position that the Podster has no utility. This simplifies its proof problem by assuming away the issue. The Commission has demonstrated expertise in product safety and a Congressional mandate to protect the public from unreasonable risk of injury, but it has not been conferred any authority to judge product utility or regulate the marketplace based on its own staff's unsupported assessment of value.

The failure to consider in any way the possible utility of the Podsters is a crippling weakness. *See Forester v. CPSC*, 559 F.2d at 790 (remanding challenged rule where Commission failed to consider utility of prohibited bicycle components); *Motor Veh. Mfrs. Ass'n of U.S. v. State Farm Mut. Ins. Co.*, 463 U.S. 29, 43 (1983) (agency action may be arbitrary and capricious where it has "entirely failed to consider an important aspect of the problem").

Complaint Counsel seeks to rely on the availability of safer products, but its own evidence shows that consumers will often choose other less safe options for infant sleep—including co-sleeping or bed sharing without a Podster or any other infant product.

B. Even if the Commission Finds that the Podster has a Design Defect, the Record Does Not Support a Finding that Such Defect Creates a "Substantial Risk of Injury to the Public."

While Complaint Counsel has failed to prove that the Podsters are defective, even if the Podsters were found to have a "defect" in the technical sense—their failure to conform to an idealized safe-sleep standard, and a common tendency to misuse the product for sleep—the products' alleged shortcomings do not create a "substantial risk of injury to the *public*."

Complaint Counsel may not be required to show that a Podster was the "but for" cause of any death. But it is incumbent on the proponent of the order here to demonstrate that a substantial risk of injury in fact exists, and that the Podster's design created the risk.

To "create" is to "bring into existence;" to "produce or bring about by a course of action or behavior;" or "to cause or occasion." Create, Merriam-Webster.com, https://www.merriam-webster.com/dictionary/create (last updated June 21, 2024). Thus, the substantial risk of injury

must actually exist, and it must have been "brought into existence," "produced or brought about by" or "caused" by a defect in the design of the Podster.

Even if the Commission were to find that the Podster's non-conformance to an idealized sleep surface it has approved is a "defect," it must yet establish that such defect creates a substantial risk of injury to the public. Here, too, its evidence falls short of its objective.

1. Complaint Counsel's Evidence has Scientific Validity But Does Not Support the Conclusion Upon Which the Complaint Rests.

Respondent has argued that the testimony of Complaint Counsel's experts should be excluded under Rule 702 of the Federal Rules of Evidence and the standard articulated in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Resp't Post-Hr'g. Br., at 25. Rule 702 may permit expert testimony from a witness qualified by knowledge, skill, experience, training, or education, but only if the testimony will be helpful to the trier of fact's understanding and determination of a fact in issue, and only where the testimony is based on sufficient facts or data, and is the product of reliable principles and methods, which have been reliably applied by the expert to the facts in the case. Fed. R. Evid. 702.

This imposes on the trier of fact a "gatekeeping" duty to ensure that the proffered testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert,* 509 U.S. at 597. The testimony must be characterized by the same intellectual rigor as an expert practicing in the relevant field. *Kumho Tire Co. v. Carmichael,* 526 U.S. 137, 152 (1999).

Complaint Counsel's witnesses have produced reams of testimony, studies, and analytical data about the potential for injury if Podsters are misused for sleep or unsupervised care. Its case in support of a purported risk is therefore not purely speculative.

While Respondent challenged CPSC experts' experience, equipment, means, and methodologies, the witnesses were each intelligent, accomplished, capable, and articulate. Their approaches and techniques were not inappropriate and were generally helpful in illustrating the issues and providing bases for understanding potential hazards.

Mannen designed, constructed, and employed numerous scientific and mechanical devices that offered reasonable approximations of the positioning and movement of infants in and on a variety of products and surfaces. She has an informed perspective on infant physiology and breathing, and the models she employed, though imperfect representations of live infants, were logically selected and used.

She thus possesses the qualifications to discuss infant physiology and biomechanics in this context. She explained how her models and techniques were developed, and how they might approximate the positioning of an infant on the product, airflow, and other factors that could have relevance in determining a product defect or hazard.

Katwa is clearly qualified to testify about the medical and physical effects of positioning based on Mannen's conclusions. Specifically, he is highly qualified to testify on infant

pulmonary function, and Mannen's research and assessments on positioning within or on various infant products provide a reasonable basis for him to testify about the hypothetical risk of injury, should the conditions Mannen projected be realized.

Respondent cross-examined Kish extensively about the fact that her surveys of public communications were not quantified, and that she could have no way of knowing how many consumers were influenced, and in what way, by any of the posted materials. But the exemplars she provided illustrated the potential for even "respected" and "medically reviewed" sources to provide misinformation. And her thoughtful and informed testimony about the propensity for even informed consumers to ignore warnings and downplay risks provided a helpful perspective on the *potential* for danger.

Complaint Counsel's case is therefore more than mere conjecture. But grounded as it is on models, hypotheticals, and unquantifiable assumptions about consumer behavior, Complaint Counsel's theory of the case is merely a hypothesis requiring proof.

Evidence may meet the standard for admissibility yet be unpersuasive. Cross examination or contrary evidence introduced by an opponent may call into question the expert's conclusions or methodology, even if the proffered testimony appeared to be sound before the hearing.

The experts who testified suggested that the nature of the product and its target audience will lead to extensive misuse for sleep, because consumers have been "pacified" or lulled into believing that such use is safe and normal (Kish); that the Podsters are unsuitable and dangerous in this role due to their physical characteristics (Mannen); and that, as a result, there is a widespread danger of suffocation, serious injury, and death (Katwa).[32]

But expert opinion has its limits, and even admissible opinions from highly qualified scientists may wither in the face of facts. As the physicist Richard Feynman aptly noted, "Science is the belief in the ignorance of experts. When someone says, 'science teaches such and such,' he is using the word incorrectly. Science doesn't teach it; experience teaches it." Richard P. Feynman and Jeffrey Robbins, The Pleasure of Finding Things Out: The Best Short Works of Richard P. Feynman, 189 (2005).

2. The Product History of the Podsters Must be Considered as Data About the Product's Relative Risk of Injury.

Experience with the Podsters over their product life refutes the conclusion posited by Complaint Counsel and advanced by its experts. The fact that no testing of the Podsters involved

[32] No individual expert possessed the qualifications and expertise to relate the entire theory, but I find that the complementary testimony of the CPSC's experts articulated, together, a cogent and tenable hypothesis. A motion had been granted limiting Katwa's testimony because he is not an expert in human factors. *See* Aug. 2, 2023, Prehr'g Order, at 6-7. *See also Alfred v. Caterpillar, Inc.*, 262 F.3d 1083, 1088 (10th Cir. 2001) (excluding testimony of witness who had no qualifications as human factors expert). However, Mannen and Kish clearly testified as to cause, while Katwa explained the potential effects within his area of (considerable) expertise.

actual, live infants does not mean that there are no data on the use of Podsters by infants. The Podsters' product history is in fact analogous to a long-term observational study testing the experts' hypothesis.

In a little more than 12 years, approximately 180,000 Podsters were distributed in commerce. The nature of the product, intended for episodic, brief support of caregivers nurturing very young infants, suggests that there have been millions—and probably tens of millions—of individual occasions when an infant has been placed on a Podster.

If consumers were prone to ignore product instructions and warnings and use the Podsters in or as an unsafe sleep environment, as Kish asserted; and if it were "easy," as Mannen testified, for infants to move into a dangerous position on the Podster, restricting their breathing physiologically or occluding their available air; and if, as Katwa testified, those infants would thus be at risk of serious injury or death from oxygen deprivation—then one would expect a profound and disturbing number of infant deaths from use of the product.

The experiential data refute that prediction. In the entire history of the Podster product line, there have been three incidents where the product was at least present in circumstances that suggested it was being or had been used where an infant died. In all those events, the product was being used in an unsafe sleep environment with compound hazards, including a lack of conscious adult supervision for a significant period.

From a purely mathematical standpoint, the risk of injury from use of the Podsters appears to be vanishingly small—even if one assumes that the Podster was a proximate cause of death in all three incidents (a conclusion not supported by the available evidence). Of course, the enormity of loss when a life is stilled so near to its beginning cannot be overlooked. But for perspective, Mannen reported that nearly 1,000 infants die in their sleep every year. CCX-1, Ex. C, at 11. Katwa testified to 3,500 such deaths.[33] The 20 products studied by Mannen in her pillow study were deemed responsible, to some degree, for 37 fatal incidents out of 47 infant fatalities where the product was present in a two-year period. CCX-1, Ex. C, at 13-15.

Other products thus appear to present the same sort of problems as the Podster, from the CPSC's standpoint, and yet have not been singled out for excision from the marketplace. This would not be a fatal omission, if the CPSC's case had focused on unique or distinctive design features rendering the Podster especially dangerous. But the absence of such evidence and reliance on features and public behaviors common to a variety of products reflects a lack of any linkage between the product itself and the dangers that could arise from its misuse.

[33] The enormous discrepancy between their estimates was not addressed by either party, but Katwa's figure does include deaths from accidental strangulation and suffocation, in addition to those attributed to SUID. While the difference is large, it is not significant to the decision because either annual figure is more than two (and in the case of Katwa's figure, more than three) orders of magnitude greater than the number of deaths that could be attributed to the Podster in its entire product lifetime.

Nowhere in Complaint Counsel's case is there a basis for concluding that a substantial risk of injury has been created by the Podster's design. Any design feature that may have contributed to the deaths—the incline, the plush, padded sides, the lack of rigid structure—is commonly found in other products.[34] Tellingly, neither Complaint Counsel nor the Commission has sought to restrict any such features, per se—an action that would seem more consistent with a focus on a design defect.

3. Complaint Counsel Need Not Show that the Podsters Caused Even a Single Death, but No Other Evidence Supports a Finding that the Podster's Design Creates or is Essential to the Unsafe Sleep Environments that Place Infants at Risk of Severe Injury.

The data do not support a substantial risk of injury to the public *created* by a defect in the Podster, as the standard requires, even if a defect were to be assumed, because there is not a single case in the record where the product itself may be identified as a but-for cause of the risk of injury, and there is no other basis for otherwise holding the product's design accountable for any risk of injury at all.

It is of course possible that there is more than one but-for cause responsible for producing an outcome. *See Bostock v. Clayton County, Ga.*, 590 U.S. 644, 656 (2020) (noting that in a hypothetical accident, errors by both drivers could each be cited as a but-for cause). But it is possible to determine, through analysis, whether a given factor has caused a result: "[A] but-for test directs us to change one thing at a time and see if the outcome changes. If it does, we have found a but-for cause." *Id.*

Here, the CPSC's own data on SUID demonstrate that the proximate cause of death in most cases is either unknown or unidentifiable, or is the result of product misuse, across product lines and types and from a variety of circumstances not directly related to the design of the diverse products involved. Thus, the risk of injury appears to be present regardless of whether a Podster is involved, because so many other deaths result from unknown causes or from the misuse of other products.

The three incidents brought to trial here as evidence against the Podster show that in each case, the product was part of an unsafe sleep environment. Two of the deaths occurred in child-care facilities, even though the Podster is intended for sale to individual consumers. Photographs collected in the IDI of the Texas incident show several other inclined infant products in the home where the child died. The CPSC did not identify or discuss any of those products, which appear similar to other products studied by Mannen and Wang.

[34] The CPSC has banned inclined infant sleep products and appears to have banned certain infant pillows. Tr. Vol. II, 35-36. *See* 15 U.S.C. § 2057d (banning "product[s] with an inclined sleep surface greater than 10 degrees that [are] intended, marketed, or designed to provide sleeping accommodations for an infant up to 1 year old.") But Complaint Counsel has not directly related those actions to the Podster, i.e., it has not claimed that the Podster is in fact an inclined sleep product or a banned infant pillow.

This is a critical omission. The incidents involving pillows and studied by Mannen for the CPSC "elucidated the **dangerous sleep** environments with every single case having two or more potential dangers identified." CCX-1, Ex. C, at 18 (emphasis in original). This blunts any argument that the problem is related to a design feature of the Podsters, because the evidence establishes the universal involvement of other causative factors in every death studied by Mannen's team.

It is also noteworthy that Complaint Counsel's case includes no direct evidence about any other infant lounger product. This is true even though Kish cited to a review in which *The Stork List* had compared the Podster to three other such products. *See* CCX-2, at 43-44; CCX-2, Ex. 8; Slip Op. at 20-21, *supra.*

The features of these products were never addressed by Complaint Counsel, even though they are discussed in a review included in its case.[35] One of the products touts the "safety" of the product as a co-sleeper, a practice disparaged as *per se* dangerous by Kish. CCX-2, Ex. 8. Another appears to have similar features to the Podster. *Id.*

The only comment on the review which Kish cited expressed gratitude to *The Stork List* for identifying a different product as "the safest [co-sleeper] on the market," and expressed unspecified concerns about the Podster. CCX-2, at 44. Kish's opinion condemned *all* of the products, based on this comment: "[T]he fact that this online review . . . was able to convince [the consumer commenting on the review] that any of these products were [sic] safe for infant sleep shows just how persuasive and potent these counter-examples can be on influencing consumer behavior." CCX-2, at 44-45.

If the misuse of the Podsters is as likely as Kish believes it to be, then the hazards and consequences predicted by Mannen and Katwa cannot be as severe as their opinions assert, or more deaths and the connection to the product would be causally associated with the Podster. On the other hand, if Kish is incorrect, and misuse of the Podster is not widespread, the Commission's case collapses because the data cannot support a theory that the product's design presents an unacceptable risk of serious injury or death in the absence of widespread misuse.

Indeed, the Commission's case is premised almost entirely on the novel argument that a general propensity for misuse of infant products for sleep may be enough, in and of itself, to support a theory of defect in *this* product. But there never has been an injury reported from the use of this product in accordance with its warnings and instructions. The three injuries (all fatalities) reported in a 12-year period, during which 180,000 of the allegedly defective products had been distributed in commerce, all. involved the inclusion of the Podster in circumstances that would have been unsafe in the eyes of the CPSC and the AAP even if the product had not been present, or if a different product with similar features were substituted.

The CPSC has established a network and a process for reporting deaths where a product may have been involved and performs in-depth investigations of those incidents where

[35] It is unclear from the review what product category the other three products falls within, but one product is touted as having "nearly perfected the art of safety in co sleepers," and another, the "Boppy Lounger" appears to be an infant lounger. CCX-2, Ex. 8 [sic].

appropriate. In that context, it does not seem likely that a significant number of premature infant deaths involving a single product line would have escaped its attention. And from a purely legal standpoint, Complaint Counsel bears the burden of supporting its proposed action against Respondent, and the evidence has failed to satisfy that burden.

4. The Relief Sought by the Complaint is an Extraordinary Imposition on Private Citizens and is Not Rationally Related to a Legitimate Government Interest.

The CPSC has identified a legitimate government interest in the Complaint. Protecting the public from a substantial risk of injury created by dangerous or defective products is at the core of its mission. But the relief sought in the Complaint would be unlikely to contribute positively to achieving that result, because it is directed at the wrong target.

It is tempting, of course, to be swayed by the tragedy authored by the death of even a single child. But the CPSC's mission and purpose must be considered as an extraordinary remedy reserved for cases where the general welfare of the public justifies the agency's extraordinary intervention, and where the evidence shows that such intervention is justified.

It does not. The weight of the evidence shows that the complex problem of infant sleep often has at its root a propensity to engage in risky behavior. The motivation for this behavior is not necessarily carelessness or neglect. As Kish testified, "New parents are usually sleep-deprived and are likely to do anything to get their infant to fall and stay asleep for more than an hour." CCX-2, at 54.

As noted above, the Commission has not pre-empted product liability law, which remains available as a means—though of course imperfect—for recompense to persons injured by an unreasonably dangerous product. Product liability lawsuits focused on dangerous product features and characteristics also may force improvement of hazardous products or their removal from the market by economic pressures and incentives arising from verdicts.

The Commission was founded in part due to the inadequacy of product safety law. *See* 15 U.S.C. § 2051(a)(4),(5). But it exists to protect the *public* (that is the people, generally[36]) from unreasonable risk of injury, not to eradicate *any* risk of injury to any member of the population. *See* 15 U.S.C. § 2051(b)(1).

The CPSC is engaged not only in enforcement or product restriction. It is part of a widespread government effort that has successfully publicized and promoted safer sleeping environments for infants, among other laudable educational pursuits.

These include not only the warnings on the Podsters, but the warnings placed on cribs, advising caregivers not to place other objects in the crib with an infant, the successful "Safe to

[36] *See* Public, Merriam-Webster.com, https://www.merriam-webster.com/dictionary/public#dictionary-entry-2 (last updated June 20, 2024) (defining "public" as "the people as a whole; POPULACE").

Sleep" campaign, and other public information and education efforts undertaken by the CPSC and other government and public health entities.

Because there are limits to every public service or information campaign, it is unlikely that the outreach required to persuade members of the public to modify their behavior. Note that Mannen was able to purchase products that had been recalled from second-hand sources for her pillow study. CCX-1, Ex. C, at 20. But the relief sought in the Complaint, to remedy effectively the statistically small number of persons who might dangerously misuse the Podsters, would need to reach persons with some propensity to ignore or disregard important product warnings and information and other government efforts to eliminate sleep hazards for infants.

Legally, there are limits to government action premised on models, rather than data. "An agency may utilize a predictive model so long as it explains the assumptions and methodology it used in preparing the model. If the model is challenged, the agency must provide a full analytical defense." *Nat. Res. Def. Council v. Herrington,* 768 F.2d 1355, 1385 (D.C. Cir. 1985), *citing Eagle-Picher Indus., Inc. v. United States Envt'l Protection Agency,* 759 F.2d 905, 921 (D.C.Cir. 1985) (footnotes omitted).

Courts may defer to an agency's judgment in using a model "if the agency examines the relevant data and articulates a reasoned basis for its decision." *Nat. Res. Def. Council,* 768 F.2d at 1385, *citing Eagle-Picher Indus., Inc.,* 768 F.2d at 921–22; *Small Refiner Lead Phase-Down Task Force v. Environmental Protection Agency,* 705 F.2d 506, 535 (D.C.Cir.1983); *Sierra Club v. Costle,* 657 F.2d 298, 332–33 (D.C.Cir.1981). The CPSC has not done so here. There appears to have been no placement of the Podster's safety record in perspective, despite the availability of data the Commission itself produced at hearing which would have permitted such an analysis.

The Complaint charges that the three deaths over a 12-year period where a Podster was present are the result of a defect. But there were nearly three dozen infant or young child deaths in a two-year period which Mannen and her team of experts found to have at least been somewhat related to use of products tested in the pillow study. That study did not isolate a common characteristic defect, or defects, which created a risk of death, but found all of the deaths to be the product of compound hazards in unsafe sleep environments.

Nor has the supposed substantial risk of injury to the public been evaluated against the nearly 1,000 infants who Mannen said die in their sleep every year, or the 3,500 annual SUIDs Katwa testified to, despite the enormous progress made through the "Safe to Sleep" program and other efforts. *See* Tr. Vol. III, 47 (citing most recent available annual data).

As Respondent notes, infants may even die in cribs and bassinets, products promoted by the CPSC for safe sleep. Resp't Post-Hg. Br., at 93-94.[37]. In that time period, coinciding with the Podster's product lifetime, 137 infants died in cribs. *Id.* The Commission said 73% of those deaths were associated with a cluttered sleep environment, including extra bedding, pillows, blankets, and other items.

[37] Respondent cites RX-20, CPSC Reports, *Nursery Product-Related Injuries and Deaths Among Children Under Age Five,* 2009-2022, at 152, Table 4.

Unlike when it develops safety standards through rulemaking, the Commission is not required to engage in cost-benefit analysis before taking action under section 15(b). *See* 15 U.S.C. § 2058(f)(2)(A) (requirement for performing cost-benefit analysis before promulgating rule). But there is nonetheless a requirement to rationally consider all aspects of the problem and, when challenged, to provide a reasoned basis for its decision.

The case against the Podster does not reflect a weighing of interests, costs, or alternative approaches that would seem to be required where consumer misuse is the primary factor (and perhaps the only relevant factor) to which any injuries involving the Podster have been attributed. *See Gulf South Insulation v. CPSC*, 701 F.2d 1137, 1148 (5th Cir. 1983), *citing Southland Mower Co.*, 619 F.2d, at 508-09 (determination of unreasonable risk of injury under CPSA involves "balancing test" like that used in tort law, weighing severity and likelihood of injury against harm produced by the regulation). In *Gulf South*, the Court found the CPSC's case deficient because it failed to demonstrate the likelihood of injury, even though the injury—cancer—was in fact severe. *Id.* The failure to quantify the risk there was the case's "Achilles' heel." *Id.*

This is not a product liability case, and the Commission rightly notes that it need not prove that the Podster was the proximate cause of any death to act against a product. The language of the Act does not require a showing of any fatalities, only a "substantial risk" of injury to the public.

However, the Commission is required to prove that a risk exists and that a defect in the Podster products "*creates*" that risk. There must therefore be proof of a product defect and a demonstrated potential for danger *to the public* caused by that defect, and the likelihood of injury must be established so that the burdens of the CPSC's proposed solution may be weighed against its benefits.

The CPSC's models and projections project a valid hypothetical for consideration: If these facts, then this result. But the Commission has failed to address the real-world, experiential data invalidating its theories about the existence of a defect or a substantial product hazard.

IV. Conclusion and Order Denying Relief Sought in Complaint

As set forth in this decision, the Commission has not demonstrated by a preponderance of the evidence that the Podsters have a substantial design or other defect and, even if a defect might be found to exist in some technical sense, the Commission has also failed to demonstrate that such defect creates or has created a substantial risk of injury to the public. The relief sought in the Complaint is therefore **DENIED**, and the Complaint is **DISMISSED.**

Michael G. Young
Administrative Law Judge

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